COMPARATIVE EVALUATION OF PHENIRAMINE VERSUS HYOSCINE FOR MANAGEMENT OF POST – OPERATIVE CATHETER RELATED BLADDER DISCOMFORT AFTER GENERAL ANAESTHESIA

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Dedicated

to

My Family,

Friends

&

Teachers

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ABBREVATIONS

ASA	AMERICAN SOCIETY OF ANAESTHESIOLOGIST
BBB	BLOOD BRAIN BARRIER
COX2	CYCLOOXYGENASE 2
CPM	CHLORPHENIRAMINE
CRBD	CATHETER RELATED BLADDER DISCOMFORT
DPNB	DORSAL PENILE NERVE BLOCK
EA	EMERGENCE AGITATION
HR	HEART RATE
IV	INTRAVENOUS
M3	TYPE 3 MUSCARINIC RECEPTORS
MAP	MEAN ARTERIAL PRESSURE
MOSS-A	MODIFIED OBSERVERS ASSESSMENT OF ALERTNESS SEDATION SCALE
NMDA	N-METHYL D-ASPARTATE
NSAID	NON- STEROIDAL ANTI INFLAMMATORY DRUGS
NSR	NUMERICAL RATING SCALE
OAB	OVERACTIVE BLADDER
PACU	POST ANAESTHESIA CARE UNIT
PCNL	PERCUTANEOUS NEPHROLITHONOMY
PGE2	PROSTAGLANDIN E2
PNB	PUDENAL NERVE BLOCKS
RTX	RESINIFERATOXIN
SBP	SYSTOLIC BLOOD PRESSURE
TURBT	TRANSURETHRAL RESECTION OF BLADDER TUMOR
TURP	TRANSURETHRAL RESECTION OF PROSTRATE

ABSTRACT

Introduction: Catheter Related Bladder Discomfort (CRBD) is a relatively common complication which is distressing both for the patient and staff in postoperative care unit (PACU). Although various agents are available for prevention as well as management of Catheter Related Bladder Discomfort (CRBD), yet there is no well-established regimen for management of it.

Objective: The present study was designed to evaluate the efficacy of Pheniramine versus (vs) Hyoscine for management of post- operative Catheter Related Bladder Discomfort (CRBD) after general anaesthesia.

Methods: Total of 60 adult male belonging to American Society of Anaesthesiologist (ASA) I and II class, posted for elective non – urological surgeries complaining of grade 2 and 3 CRBD in post-operative period were enrolled for a prospective, double blinded, randomized study. The technique for general anaesthesia was standardized in both groups. Group A received Injection Pheniramine 22.75 mg intravenous (IV) and group B received Injection Hyoscine 20 mg IV.The patients were observed for 6 hours to compare the severity of CRBD, rescue analgesic requirements and adverse effects.

Results: The demographic characters in both the groups were similar. There was significant difference between the two groups in the severity of CRBD. Severity of CRBD in Group A at 2, 3, 4 and 5 hours was 1.13±0.82, 0.50±0.94, 0.27±0.64 and 0.10±0.31respectively while in Group B it was1.80±0.61, 1.40±0.72, 1.00±0.79 and 0.53±0.57 (p value 0.001). Tramadol requirement was also reduced in Group A (5mg±15.26) as compared to Group B (48mg±40.44)(p value 0.001). Moreover, incidence of adverse effects was lesser in Group A(6.7%) than in Group B (33.3%) and all these adverse effects resolved spontaneously within 6 hours. Mean NRS for surgical site pain, need of fentanyl, mean sedation score was also lesser in Group A than in Group B.

Conclusion: IV Pheniramine is more efficacious than IV Hyoscine for management of post-operative CRBD without any significant adverse effects.

Key words: Pheniramine, Hyoscine, Urinary Catheterization, Post-operative, Catheter Related Bladder Discomfort (CRBD), General Anaesthesia.

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INTRODUCTION

Urinary catheterization is a commonly performed procedure in hospitalized patients especially for those undergoing prolonged surgical procedures under anaesthesia. Inserting an indwelling urethral catheter after the induction of general anaesthesia has many advantages which include avoidance of psychological tension, discomfort, pain and embarrassment caused by urethral catheter insertion. However insertion after general anaesthesia does not mitigate the discomfort caused by urinary catheter in the post-operative period. In addition to the well-known adverse effects of urinary tract infection associated with bladder catheter; patients can also experience catheter related bladder discomfort (CRBD).

CRBD is defined as an urge to void or discomfort in the suprapubic region reported post-operatively in patients who are awakening from anaesthesia and have had urinary catheterization intraoperatively. It is characterized by a sensation of frequent and urgent urination, which is similar to overactive bladder syndrome (OAB). The incidence of CRBD is 47–90% in patients who have undergone elective surgery. [1] The incidence of CRBD is higher in the early post-operative period compared with the late post-operative period.[2] CRBD above a moderate grade is often intolerable and requires treatment and is experienced by 38–57% of patients with a urinary bladder catheter in post-anaesthesia care unit (PACU). [3]

Indwelling urinary catheter size (> 20F) and male gender are known independent predictors of CRBD above a moderate grade in the PACU. [4]Surgery type is also regarded as one of the risk factors for CRBD with higher incidence reported after urological, gynaecological and open abdominal surgeries.[5]CRBD is most likely to cause restlessness in patients during the waking period and is prone to adverse consequences, such as prolapse of drainage tubes, falling from the bed, and incision dehiscence. CRBD can cause tachycardia and elevated blood pressure. Clinical studies have shown that tachycardia and elevated blood pressure might lead to cardiovascular

and cerebrovascular accidents and endanger life. [6,7] Therefore, CRBD is an important issue in the PACU.

CRBD can be so disturbing to patients that it is accompanied by post-operative agitation, poor satisfaction of the hospital stay, increased cost due to prolongation of PACU stay and an increased workload for medical staff. However CRBD is frequently neglected and left untreated clinically. [1, 4, 8-10] Management of CRBD is beneficial in improving patient's comfort and reducing post-operative emergence agitation (EA) and pain. Despite the existence of various treatment and prevention options for CRBD, many uncertainties still persist in clinical practice. For instance, an effective treatment for CRBD without adverse effects is yet to be established. There is a paucity of evidence in the medical literature regarding the efficacy and safety of drugs in treating symptoms of CRBD. Therefore, there is a need to find an effective treatment which can enhance quality of life of patients post-operatively.

A better understanding of CRBD and its pathophysiology may lead to better management and decreased morbidity. Though the exact mechanism of CRBD is not known but studies have pointed towards the role of muscarinic receptors in this. [11]CRBD is induced by involuntary contractions of the urinary bladder mediated by type 3 muscarinic (M3) receptors.[12] M3 receptor leads to direct contraction and the M2 receptor is associated with indirect contraction of the bladder.[13] There is evidence to suggest that muscarinic receptors located in the urothelium/suburothelium and on afferent nerves contribute to the pathophysiology of OAB and CRBD.[14] Recently, increased urinary levels of prostaglandin E2 (PGE2) have been postulated to contribute to the symptoms of CRBD.[15,2] The presence of urinary catheter and the mucosal layer damage could trigger local inflammation with increased activation of cyclooxygenase-2 (COX-2) enzyme and release of PGE2.[16] Capsaicin-sensitive C fibres which are activated by prostaglandins contract the bladder's detrusor muscle. Calcitonin gene-related peptide nerve fibres, which regulate the immune system, are located in bladder smooth muscle. All these receptors play role in the pathogenesis of CRBD.

Various muscarinic receptor antagonists including ketamine, tolterodine, tramadol, butyl scopolamine, robinul and dexmedetomidine have been evaluated for their ability to prevent the CRBD with varying degrees of success. However, they induce adverse effects such as dry mouth, sedation, post-operative nausea and vomiting, facial flushing, and blurred vision especially in the elderly. Therefore, drugs from various other classes such as narcotic analgesics, including tramadol, lidocaine gel and dezocine have attracted the attention of researchers. Antiepileptic drugs including gabapentin and pregabalin, have been found to prevent or treat CRBD symptoms. Other drugs including analgesics (Paracetamol) and recently anaesthetics (Sevoflurane) have been found to be effective in reducing the incidence and the severity of CRBD.

In contrast to post-operative pain, CRBD is resistant to conventional pain management such as opioids because different mechanisms are involved in developing post-operative pain and CRBD .In addition to drug intervention, basal and caudal nerve blocks and dorsal penile nerve block have been proven to have significant therapeutic effects for CRBD. However, these are invasive procedures and there is a risk of neuronal damage . Moreover, these nerve blocks requires competence and practise and yet these blocks can be technically challenging to be placed in patient suffering from CRBD who is restless and irritable. Despite the availability of these drugs and treatments, the incidence rate of CRBD in existing studies remains as high as 32–69% even after drug intervention.

Therefore, to improve patient's experience, we need to determine a more rapid and safe way to effectively treat and prevent CRBD.

Hyoscine butyl bromide (Butyl scopolamine) was patented in 1950 and approved for medical use in 1951. It is on the World Health Organization (WHO)'s list of essential medicines. Hyoscine, an anticholinergic drug, is a quaternary ammonium derivative which has a high affinity for muscarinic receptors located in the smooth muscle cells of the gastrointestinal tract and it has been used to treat abdominal cramps.[17] It has incidentally been found to be effective against CRBD.

In addition, hyoscine does not cross the blood–brain barrier (BBB) because of the attachment of butyl bromide, therefore central side effects such as blurred vision and flushing of the face are averted. [17] The mechanism by which hyoscine relieves CRBD may be explained by its anti-muscarinic, anti-spasmodic and relaxant effect on the bladder. Hyoscine is known to have a high affinity for human M2 and M3 muscarinic receptors subtypes. The onset of IV. hyoscine is about 9 min with a peak action at 20-60 min and an elimination half-life ranging from 1 to 5 hours. [17]

The property of Diphenhydramine to produce antihistaminic as well as antimuscarinic effect was used by Yu-Yu Li et al to successfully attenuate post-operative CRBD without significant side effects in patients undergoing gynaecologic laparoscopic surgery when given prophylactically.[18] Diphenhydramine is a first class antihistamine which comes under highly sedative category and sold under the brand name as Benadryl. Chlorpheniramine (CPM) is also a first-generation antihistamine that is widely used for symptomatic relief of allergic conditions .Its action is achieved by inhibiting H1 receptors on cells, antagonizing the reversible effects of histamine, and competitively inhibiting the target organ. First-generation antihistamines are also competitive inhibitors of muscarinic receptors and have anticholinergic effects .In addition, antihistamines potentiate analgesic effect of other analgesics. Peak plasma concentrations after the IV administration of CPM are achieved after 15 min, with plasma half-lives of 8–17 h. [19] Because CPM readily penetrates the BBB and acts on central H1 receptors, it has a potential to cause adverse central nervous system effects such as sedation, somnolence, and cognitive impairment, and its antimuscarinic effects can cause symptoms, such as dry mouth and blurred vision. Pheniramine belongs to same antihistamine class and, possesses properties similar to CPM and diphenhydramine. Therefore, we hypothesize that IV pheniramine could be efficacious for management of CRBD.

Hyoscine is a prototype anti-muscarinic drug without central nervous system penetration, is widely available and used in anaesthesia

practise. On the other hand, pheniramine is a potent anti-histaminic drug that has not been studied at all with respect to CRBD .Hence we plan to study and compare the efficacy of IV pheniramine and IV hyoscine for treatment of post-operative CRBD after general anaesthesia.

AIMS AND OBJECTIVES

To compare the efficacy and safety of Pheniramine and Hyoscine in terms of:

- Management of CRBD.
- Post-operative analgesic requirements.
- Adverse effects.

REVIEW OF LITERATURE

Urinary catheterization is the one of the commonest procedure performed in hospitalized patients. However, patients often complain of CRBD after urethral catheterization. The factors predisposing patient to the occurrence of CRBD include: - age<50 years, male gender, urinary size catheter size>20 F, urological, gynaecological, obstetric and open abdominal surgeries. [5]

The symptoms of CRBD are similar to those of OAB such as pain and discomfort in the suprapubic region, frequency, urge to void and a burning sensation with or without urge incontinence. These symptoms are usually very distressing to the patient, their relatives, and staff in the PACU. Severe CRBD is associated with behavioural responses such as a exaggerated vocal response, flailing extremities and an attempt to pull out the urinary catheter. Severity of CRBD is graded from 0-3. Grade 0 means no discomfort reported on questioning; grade 1 indicates mild discomfort, reported by patient only on questioning; grade 2 reflects moderate discomfort, reported feeling of urgency of urination without questioning but not accompanied by any behavioural response and grade 3 is severe discomfort, reported by patient without asking and accompanied by behavioural responses such as attempts to remove the urinary catheter, restless extremity movements or verbal responses. [8]

Owning to high incidence of CRBD, prophylaxis and effective management is extremely important. Various interventions have been employed for its management.

ANAESTHESTIC DRUGS

Ketamine (a phencyclidine derivative) is a well-known anaesthetic agent which has its action through multiple binding sites, including n-methyl d-aspartate(NMDA) and non-NMDA glutamine receptors, mono-aminogenic and opioid receptors, nicotinic and muscarinic cholinergic receptors.[20] Based on its action on muscarinic cholinergic receptors Agarwal et al in 2006 conducted study on ketamine for treatment of CRBD and reported that ketamine (250mcg/kg) reduced

the incidence of CRBD (p value< 0.001) at 2 hour and 6 hour along with reduction in severity (p value <0.05) at 1 hour compared with control group. They also observed that higher incidence of mild sedation was observed in the ketamine group (p value <0.05) which was not associated with any untoward effects. Operative time and intraoperative fentanyl requirement were similar in both the groups. The limitation of this study was that the effect of the lower doses of ketamine for treatment of CRBD was not investigated.[21] Hence in 2012 Safavi et al conducted study on evaluation of the efficacy of different doses of ketamine for treatment of CRBD in patients who underwent urologic surgery using three doses of ketamine i.e. 150 mcg/kg, 200mcg/kg and 250mcg/kg and concluded that IV ketamine (200 mcg/kg) had similar efficacy to IV ketamine (250 mcg/kg) in reducing the severity of CRBD without the occurrence of significant side effects. All these three doses compared the efficacy and safety of ketamine with placebo. [22]

In 2013 Shariat et al studied effects of intra-operative ketamine administration on occurrence of post-operative CRBD and observed that pre-emptive administration of IV ketamine (0.5 mg/kg) can reduce the incidence and severity of CRBD in the early post-operative period (at 0 and 1 hour). However, no significant differences were observed between the two groups at the 2 and 6-hour evaluations. [23]

In 2016 Burimsittichai et al compared IV tramadol and ketamine for prevention of CRBD after laparoscopic surgery and concluded that the IV administration of tramadol 1.5 mg/kg or ketamine 0.5 mg/kg before urinary catheterization reduced the severity of CRBD at 6 and 24 h after elective laparoscopic surgery and 24-h cumulative pain of CRBD without increasing the incidence of adverse effects. Tramadol also appeared to reduce the proportion of patients reporting post laparoscopy shoulder pain. [24]

Similarly Akca et al in 2016 compared efficacy of prophylactic ketamine and dexmedetomidine on post-operative CRBD and came to conclusion that dexmedetomidine and ketamine had similar analgesic effects in preventing catheter related pain. Dexmedetomidine however

had a more acceptable adverse effect profile. The hallucinations experienced in ketamine group were especially troublesome for the patients. [25]

Salama et al in 2017 compared ketamine with hyoscine for management of post-operative CRBD and postulated that IV hyoscine 20 mg is more effective in controlling CRBD than ketamine (0.25 mg/kg) in the initial 30 min. [26]

Lu et al in 2022 performed meta - analysis on efficacy and safety of ketamine on post-operative CRBD concluded that a sub-hypnotic dose of ketamine decreases the incidence and severity of post-operative CRBD without causing significant side effects. [27]

Therefore, despite being efficacious, adverse effect profile especially hallucinations and behavioural effects of ketamine are a limiting factor preluding its routine use for management of CRBD.

ANTIEPELEPTIC DRUGS

Mainly two antiepileptic drugs – gabapentin and pregabalin have been studied for prevention of post-operative CRBD. Agarwal et al in 2007 studied efficacy of gabapentin for prevention of CRBD and compared it with control group. The authors postulated that gabapentin by inhibiting peripheral sensation and activity on C- fibres may help in treatment of OAB and CRBD. They reported that oral gabapentin (600 mg) when administered in patients undergoing percutaneous nephrolithonomy (PCNL) reduced the incidence (80% in the control group and 50% in the gabapentin group) and severity of CRBD, the number of patients requiring fentanyl and total post-operative fentanyl administration. [28]

Bala et al in 2012 studied efficacy of gabapentin for prevention of post-operative CRBD. They studied its efficacy in patients undergoing transurethral resection of bladder tumor (TURBT) and reported a decrease in the incidence of CRBD following TURBT from 90% (placebo group) to 66% in the 600 mg gabapentin group which was further decreased to 26% in the 1200 mg group. Furthermore, none of the patients in the 1200 mg group complained of bladder discomfort after 6 hours. The CRBD severity was also less in the gabapentin

group compared with the control group and none of the patients experienced severe discomfort. [29]

Maghsoudi et al in 2018 compared the efficacy of tolterodine and gabapentin vs placebo in CRBD after PCNL and concluded that preoperative administration of oral tolterodine or gabapentin reduces post-operative CRBD and the need for rescue analgesics by as much as 24 hours after surgery. [30]

Meta-analysis conducted by Wang et al in 2021 on gabapentin concluded that preoperative oral gabapentin when used as an adjunct to surgery is effective in decreasing the risk and severity of CRBD over a short time after surgery, and it can also decrease post-operative pain without significant side effects.[31]

Pregabalin, another antiepileptic, was evaluated by Srivastava et al in 2014. They studied it's efficacy for prevention of CRBD in patients undergoing spine surgeries and observed that the incidence of CRBD was significantly less in the pregabalin group compared with the control group at all-time intervals. The severity of CRBD was reduced in the pregabalin group compared with the control group at all-time intervals except 6 hours. The post-operative consumption of fentanyl was also significantly less in pregabalin group, while the sedation score was significantly higher in the pregabalin group compared with the control group. So the authors concluded that oral pregabalin (150 mg) administered 1 hour before induction of anaesthesia significantly reduced the incidence and severity of CRBD along with a reduction in post-operative fentanyl consumption, but at the cost of increased sedation. [32]

Hence gabapentin and pregabalin although has been found to effective in managing CRBD yet their efficacy in treating CRBD without deleterious adverse effects is yet to be proven in further studies.

NON- STEROIDAL ANTI INFLAMMATORY DRUGS (NSAIDS)

Urinary catheter and mucosal injury induces local inflammation with the activation of the cyclooxygenase pathway and release of prostaglandins. Hence anti-inflammatory agents such as paracetamol

and ketorolac are known to be effective in the management of post-operative CRBD.

Elevated urinary levels of PGE2 in patients with OAB and lower urinary tract obstruction suggest that PGE2 may play a role in these clinical entities. PGs are produced in detrusor muscles and mucosa and play an important role in the regulation of lower urinary tract functions. PG synthesis has been shown to be triggered by physiologic stimulations such as detrusor muscle contraction, damage in the bladder mucosa, nerve excitation, and activity of inflammation mediators such as bradykinin.The mechanism of elevated PG synthesis during CRBD may be the increased activation of COX-2 enzyme. Thus, an elevated PGE2 level may lead to the occurrence of CRBD with lower urinary tract symptoms such as urinary urgency, frequent urination, and urge incontinence.

Ergenoglu et al in 2012 studied the effect of intraoperative paracetamol on prevention of CRBD and found that a single intraoperative dose of IV paracetamol (15 mg/kg) decreased the severity of CRBD and total meperidine (rescue analgesic) administration. The paracetamol group had significantly lower CRBD scores at 1, 2, 4, and 6 hours post-operatively compared with the placebo group ($p < 0.05$). Total meperidine consumption was also significantly higher in the placebo group (75.81 mg vs 52.72 mg; $p = 0.018$) and no patients receiving paracetamol required rescue analgesia. [15]

Parecoxib a highly selective COX-2 inhibitor, can improve the symptoms of CRBD. It acts by reducing the surrounding inflammatory response, regulating nociceptors, and attenuating central sensitization. [33] It is an injectable inactive prodrug of valdecoxib. Jendoubi et al in 2018 studied efficacy and safety of parecoxib for prevention of CRBD in patients undergoing TURBT and concluded that single IV injection of parecoxib sodium (40) mg is safe and effective in decreasing the incidence and severity of CRBD. [34]

Nefopam is a centrally acting non-opioid, non-steroidal, anti-nociceptive drug, commonly used as a perioperative analgesic agent. [35] If administered during the perioperative period, it reduces the use of

opioids and NSAIDS employed for analgesia and post-operative complications such as respiratory depression, sedation and renal toxicity. The mechanism of action of nefopam is not fully elucidated; however, its central analgesic effect might be mediated by inhibiting the reuptake of serotonin, dopamine, and norepinephrine. [36,37] Cheon et al in 2018 studied effects of nefopam on CRBD and concluded that IV administration of nefopam in patients undergoing ureteroscopic litholapaxy reduced the incidence and severity of CRBD, post-operative pain, and analgesic requirements without side effect.[38]

Ketorolac tromethamine, a NSAID, induces a decrease in prostaglandin levels driven by the inhibition of cyclooxygenase. Ketorolac is widely used as an analgesic in various clinical practices. In particular, multimodal analgesia including ketorolac is recommended for effective post-operative pain management. Park et al in 2019 studied effect of ketorolac on the prevention of CRBD and concluded that ketorolac reduced the incidence of CRBD above a moderate grade in male patients. In addition, 30 mg ketorolac administered intravenously during surgery was not associated with any adverse effects. These results suggest that ketorolac administration is an effective and safe option to prevent CRBD above a moderate grade in male patients undergoing urological surgeries who require urinary catheterization. [2]

OPIOIDS

Tramadol is a centrally acting, synthetic opioid analgesic with weak opioid agonist properties. It inhibits the detrusor activity by inhibition of type-1 muscarinic (M1) and M3 receptors. Tramadol is a potent analgesic routinely used for post-operative pain relief with minimal respiratory depression, major organ toxicity, depression of gastrointestinal motility, and low risk of abuse. Epidural tramadol increases the compliance, capacity of bladder and delays filling-sensation; thus, might decrease the need of catheterization of urinary bladder in the post-operative period. Tramadol has an advantage of no effect on cognitive function and it does not produces hallucination like

ketamine. Aggarwal et al in 2008 evaluated tramadol for the prevention of CRBD. They reported that both the incidence and severity of CRBD was reduced in the tramadol group at 0, 1, 2, and 6 hours following surgery compared with the control group. Furthermore, total post-operative fentanyl requirement was reduced in the tramadol group compared with the control group (176 vs 210 mcg/kg, $p < 0.05$). Therefore, the authors concluded that IV tramadol (1.5 mg/kg) administered 30 minutes before extubation decreased the incidence (50%) and severity of CRBD and post-operative fentanyl requirement (20%).[39] Unfortunately, they did not evaluate the dose– response titration or the effect of tramadol in treating CRBD.

Another study conducted by Li et al in 2018 on tramadol for CRBD observed that tramadol 1.5 mg/kg was more effective than tramadol 1mg/kg in treating CRBD and reducing post-operative pain without significant side effects. [40] But this study had some limitations .First, they did not evaluate the efficacy of tramadol for all types of surgeries and different surgeries might have different degrees of interference. Moreover, they only observed up to 6 h after the drug was administered. Although there was no difference in the severity of CRBD among the three groups at 6 h, the half-life of tramadol is 6 h; thus a longer observation time may be necessary. In addition, all the patients enrolled in this study were women, so this results cannot be generalized to male population since males are at higher risk of developing CRBD.

Dezocine interacts with three major opioid receptors, i.e., μ, κ and δ, and the unique molecular pharmacological profile of dezocine as a partial μ receptor agonist reduces its adverse reactions in comparison with other pure opioids. Dezocine has been proven to be effective in relieving moderate to severe surgical pain. CRBD is usually resistant to conventional opioids, however, the activation of κ receptors by dezocine may contribute to the improvement of CRBD. In addition, dezocine did not increase the overall incidence of post-operative nausea and vomiting, dizziness, respiratory depression, over sedation or hypotension/ hypertension. Zhang et al in 2019 studied dezocine for

prevention of CRBD and concluded that dezocine administration before the end of surgery attenuated the incidence and severity of CRBD without inducing severe adverse effects for patients undergoing elective abdominal surgery with general anesthesia.[41]

Butorphanol is an opioid, a K receptor agonist, and a μ receptor antagonist. K receptor is an important regulator of visceral pain. After the IV injection of butorphanol, the effect starts at 1–5 min (mean 3 min), peaks at 30 min, and has a half-life of 3-4 h. [42] It has the advantages of a strong analgesic effect, long analgesic duration, mild gastrointestinal side effects, less respiratory inhibition, and low drug dependence. Lin et al in 2021 compared tramadol in a dose of 1.5 mg/kg with butorphanol in a dose of 0.02 mg/kg for treating CRBD and concluded that compared with tramadol therapy , butorphanol treatment effectively lowered the CRBD score and reduced post-operative pain. But because of its strong sedative effect, some elderly patients were in state of somnolence after the effect of butorphanol. Thus, the evaluation of post treatment of CRBD score may not had been completely accurate. [43]

PUDENAL NERVE BLOCKS (PNB)

Anatomically, the afferent nerves of the urethra and bladder triangle are derived from sacral somatic nerves (S2–S4 segment) and theoretically, prevention of CRBD should be achieved by blocking these nerves. The pudendal nerve, the main nerve of the perineum, is derived from the ventral rami of the second, third, and fourth sacral spinal nerves; innervates the urethral sphincter and muscles of the perineum and pelvic floor. It provides sensation to the penis in males and the clitoris in females, as well as to the urethra and bladder. Clinically, PNB has been applied for analgesia of labor, vaginal birth, vaginal repair, sphincterotomy and treatment of pudendal neuralgia, and the safety and effectiveness of PNB have been identified.

Li et al in 2016 studied dorsal penile nerve block (DPNB) with ropivacaine for reducing post-operative CRBD in male patients after emergence from general anaesthesia. They observed that DPNB

though significantly reduced the incidence and severity of CRBD, 3 patients still kept complaining of CRBD. Hence they postulated that effective DPNB did not offer full CRBD prevention and further studies should focus on the efficacy of PNB. [44]

Xiaoqiang et al in 2017 compared nerve stimulator-guided PNB versus no intervention in the control group in adult male patients undergoing lower urinary tract surgeries and found significantly lower incidence and severity of CRBD in the PNB group for the first 8 hours post-operatively. The pain relief was also better in the PNB group till 12 hours post-operatively. They also warned that the complications of nerve blocks cannot be neglected. [3]

Rath et al in 2022 studied role of PNB for prevention of CRBD in male paediatric patients and compared it with IV butylscopolamine and concluded that PNB seems to be superior to IV butylscopolamine in reducing and incidence of CRBD. However the concerns about potential complications of ultrasound- guided PNB like neurovascular injury, bleeding, haematoma, infection, local anaesthetic toxicity still remain. [45]

Wang et al in 2022 studied effect of PNB on the prevention of post-operative bladder spasm and CRBD in male patients undergoing urological surgery and came to conclusion that ultrasound-guided PNB at the entrance of the pudendal canal bilaterally can successfully reduce bladder spasm and CRBD and the severity of CRBD as well as providing pain relief. These results suggest that PNB is an effective and safe option to prevent bladder spasm and CRBD in male patients undergoing urological surgery who require a large-diameter urinary catheter. [46]

APPLICATION OF LIDOCAINE-PRILOCAINE CREAM

Mu et al in 2017 studied lidocaine-prilocaine cream in reduction of CRBD in male patients during the general anaesthesia concluded that topical anaesthetic lidocaine-prilocaine cream applied on urethral mucosal surface is an effective and safe tool for reducing incidence and severity of CRBD. [47] It is also patient friendly and is cost effective.

But this study had some limitations as it was not a double blinded study so bias cannot be ruled out and secondly patient were usually observed for less than one hour .Therefore the duration of beneficial effect of it was not evaluated. In addition, in the light of knowledge that receptors mediating CRBD are located in urinary bladder mucosa, it is inexplicable how local anaesthetic cream application would be more effective in the management of CRBD.

STEROIDS

Synthetic glucocorticoids like dexamethasone inhibits acetylcholine releasing by increasing inhibitory M2 muscarinic receptors function and regressing prostaglandin synthesis. Cho et al in 2022 studied effects of dexamethasone on CRBD and EA. They observed that it failed to decrease the incidence or severity of either CRBD or EA. Furthermore the anti-inflammatory, antiemetic, analgesic effects of dexamethasone which were thought to be beneficial were also not statistically significant. Although there was no statistical difference the type of surgery, sex, and diameter of the urinary catheter, which are risk factors for CRBD, were not the same in both groups, which may have affected the incidence and severity of CRBD. They concluded that future studies controlling these factors are needed.[48] Finally, sample size was small and thus it is possible that a type II error occurred. Therefore, further research with greater numbers of subjects is necessary to confirm the statistical significance of the differences in EA between the groups.

MAGNESIUM

Magnesium is the fourth most abundant cation in the body. Magnesium is related to diverse biochemical reactions, such as signal transduction in cell membranes, protein synthesis, muscle and nerve transmission, neuromuscular conduction, blood pressure regulation, and blood glucose control. Moreover, magnesium is important for the reduction and stabilization of smooth muscle contraction because it plays a key role in the active transport of calcium ions across cell membrane. Park

et al in 2020 conducted study on magnesium for prevention of CRBD in patients undergoing TURBT and concluded that magnesium reduced the incidence of CRBD above a moderate grade and increased satisfaction in patient's having TURBT. [49]

RESINIFERATOXIN (RTX)

A C fibre neurotoxin, RTX is an extract from the latex of Euphorbia resinifera. It is an ultra-potent capsaicin analogue, and has a significant advantage of being less irritable. It has the capacity to excite and then to desensitize type C primary afferent fibers. Mechanisms by RTX include: decreases in sensory input conveyed in bladder C-fibers, and decreases in the number of spinal neurons that become excited by bladder stimuli. Zhang et al in 2011 studied this drug for prevention of CRBD in patients after transurethral resection of prostrate (TURP) and concluded that a single intravesical administration of 40 mL of RTX before TURP reduced both incidence and severity of post-operative CRBD via desensitization of bladder. They also stated that whether using a higher dose of RTX or repeated intravesical instillation RTX may reduce incidence and severity of CRBD more significantly requires further investigation. [50]

ANTIMUSCARINIC AGENTS

As has already been discussed, the mechanism underlying the occurrence of CRBD is the activation of muscarinic acetylcholine receptors by the simulation of the urinary bladder catheter. Yasuhiko in 2000 highlighted that CRBD is mediated by muscarinic receptors, especially the subtype M_3 receptor. [12] Anti-muscarinic agents have been found to be useful in prevention of CRBD by decreasing both contraction frequency and intensity of bladder through reduction in over activity of detrusor muscles. Bala et al in 2012 suggested agents with antimuscarinic properties, such as oxybutynin, tolterodine, and butylscopolamine are the mainstay treatment to reduce both the incidence and severity of CRBD.[29] However, these drugs are associated with anticholinergic adverse events.

Agarwal et al in 2006 conducted study in patients requiring urinary bladder catheterization after PCNL surgery. They intervened 1 hour before surgery by giving them 5 mg oral oxybutynin and observed the incidence of CRBD. The results showed that the incidence of CRBD in the control group was higher (58%) compared with oxybutynin group (35%). A significant reduction in the severity of CRBD was also observed with oxybutynin therapy compared with placebo. [51]

Tauzin-Fin et al in 2007 studied sublingual oxybutynin for reduction of post-operative pain related to indwelling bladder catheter after radical prostatectomy and observed that sublingual oxybutynin (5 mg, every 8 h) was effective for decreasing post-operative bladder catheter related pain in 46 patients undergoing radical prostatectomy. [52] But in this study bladder discomfort and surgical wound pain were in same area making it difficult to distinguish between these two types of discomfort.

Hyoscine an anticholinergic drug is well absorbed from gastrointestinal tract and conjunctival membranes. It blocks the action of acetylcholine at parasympathetic sites in smooth muscle, and secretory glands. Both its primary therapeutic effects and its side effects are based on this. It has been used to treat abdominal cramps and has been found effective against CRBD as well.

JH et al in 2013 studied efficacy of butylscopolamine for treatment of CRBD and results showed that severity of CRBD observed in butylscopolamine group was significantly lower compared with placebo group. [53] However the study had some limitations. The patients were catheterized with different sizes of urinary catheters. In addition various urologic surgeries were included. It is known that larger urinary catheter size and urological surgery are associated with higher risk of CRBD.

Zhang et al in 2014 focused on the evaluation of solifenacin in the management of CRBD and stated that solifenacin can be beneficial for management of CRBD. [54] However the study does not distinguished between symptoms of chemical cystitis and CRBD.

Nam et al in 2015 assessed the presence and severity of CRBD at 1, 2, and 6 hours post-operatively of 99 patients with/ without

butylscopolamine prophylaxis. The results showed that the overall incidence of CRBD was less in the butylscopolamine group compared with the control group (31% vs 66%, respectively; p = 0.001). [55]

Extended release preparation of trospium chloride were tried by Srivastava et al in 2020 when they studied trospium for prevention of CRBD and reported that pre-treatment with 60 mg extended release trospium reduces the incidence as well as severity of CRBD in early post-operative period. They stated that research on the effectiveness of different dosages of trospium, durations of more than 6 hours and their effect on patient's sex in decreasing the incidence and severity of CRBD score needs further investigation.[56]

The property of Diphenhydramine to produce antihistamine as well as antimuscarinic effect was used by Yu-Yu Li et al in 2020 to successfully attenuate post-operative CRBD without significant side effects in patients undergoing gynecologic laparoscopic surgery when given prophylactically.[18]

CPM is a classic first-generation antihistamine often used to relieve allergic symptoms caused by histamine. First-generation antihistamines are also competitive muscarinic receptor inhibitors and have anticholinergic effects.

In et al in 2020 studied effects of CPM on CRBD in patients undergoing ureteroscopic stone removal and concluded that administering IV CPM (8 mg) before the induction of anaesthesia reduced the post-operative incidence of moderate CRBD. Moreover a single dose of CPM reduced the total usage of post-operative rescue tramadol for controlling CRBD during the post-operative period. [57]

MATERIALS AND METHODS

SOURCE OF DATA

This study was conducted in a randomized, double blinded manner. A total of 60 adult male patients aged 25-55 years belonging to American society of anaesthesiologist (ASA) grade I and II posted for elective non-urological surgeries under general anaesthesia who were catheterized and complained of CRBD were enrolled in the study, after approval from institutional ethics committee .Written, informed consent was obtained from all patients.

METHOD OF COLLECTION OF DATA

Inclusion Criteria

1. Adult male patient between 25-55 years of age posted for elective non- urological surgeries under general anaesthesia.
2. ASA Class I-II.[58]

Exclusion criteria:

Patients were excluded from this study if they had any of the following:

1. Clinical evidence of previous lower urinary system diseases needing medical or surgical intervention (such as prostate diseases or urethral stricture),
2. History or current evidence of urinary tract infection (UTI).
3. Bladder outlet obstruction, overactive bladder (urination frequency > 3 times/night or > 8 times in 24 h)
4. Patients already on alpha 1 adrenergic antagonists like tamsulosin.
5. Any difficulty or resistance encountered during catheterization.
6. Morbid obesity (body mass index over 40).
7. Chronic renal failure.
8. History of ischemic heart disease, myocardial infarction, hepatic or psychiatric disease.
9. History of substance abuse, chronic pain or gabapentin use.
10. History of neurologic disease like stroke, parkinsonism, alzeihemer's.

11. History of Bronchial asthma or thyroid disease.
11. History of narrow angle glaucoma.
12. Patients with catheter in-situ before shifting to operating room.
13. History of drug allergy to Diclofenac, Pheniramine and Hyoscine.

PRE ANAESTHETIC CHECKUP

All patients underwent a thorough pre-anaesthesia evaluation. Complete blood count (CBC), renal function tests, random blood glucose levels, prothrombin time (PT), activated partial thromboplastin time (PTTK), electrocardiogram (ECG) and chest X-ray were performed for all patients. Patients were informed about the use of Numeric Rating Scale (NRS) as a tool for post-operative pain assessment, and that they can request analgesic at any time if they have pain. They were also educated to distinguish between post-operative pain at the wound site and CRBD.

ANAESTHESIA TECHNIQUE

All patients were kept nil per orally for 8 hours prior to surgery and pre-medicated with oral alprazolam 0.5 mg at bed time on the night prior to surgery. In the operating room IV access was secured. Standard monitoring in the form of Electrocardiogram (ECG), Heart Rate (HR), Arterial Oxygen Saturation (SpO2), Non Invasive Blood Pressure (NIBP) and end tidal carbon dioxide (EtCO2) were carried out. These parameters were monitored throughout the procedure and recorded at an interval of 5 minutes. General anaesthesia was induced with IV midazolam 1 mg, IV fentanyl 2 µg/kg and IV propofol 2 mg/kg. Atracurium 0.5 mg/kg IV was used to facilitate orotracheal intubation. Anaesthesia was maintained with 60% N2O in O2 and IV fentanyl 0.5 - 1 mcg/kg as required. The muscular relaxation was maintained with IV atracurium 5 mg bolus every 15- 20 minutes. Ventilation was adjusted to maintain $EtCO_2$ between 30 and 40 mm Hg. Isofluarne concentration was titrated to maintain mean arterial pressure within 20% of pre-anaesthetic levels. Intra-operative management of patient including fluid and additional fentanyl administration was at the discretion of

anaesthesiologist managing the case as per standard anaesthesia technique.

A 16 French Foley's catheter was inserted in all patients after adequate lubrication of urethra with lignocaine jelly and the balloon inflated with 10 ml of distilled water. The urinary catheter was fixed with an adhesive tape without any traction and drained into a urinary bag. All patients were administered IV diclofenac 75 mg at the beginning of skin closure. On completion of surgery, neuromuscular blockade was reversed with IV neostigmine 0.05 mg/kg and IV glycopyrrolate 0.01 mg/kg, trachea extubated and patients transferred to the PACU. Paracetamol and tramadol were not administered intra-operatively.

The time of shifting of patients to PACU was labelled as time '0' and patients were followed up by an anaesthesia resident for symptoms of CRBD for up to 6 hours.

The severity of CRBD was described as:

Grade 0 – No discomfort reported on questioning.

Grade 1 – Mild discomfort, reported by patient only on questioning.

Grade 2 – Moderate discomfort, reported feeling of urgency of urination without questioning but not accompanied by any behavioural response;

Grade 3– Severe discomfort, reported by patient without asking and accompanied by behavioural responses such as attempts to remove the urinary catheter, restless extremity movements or verbal responses.

Patients complaining of CRBD grade 2 or 3 were enrolled for the study and randomly allocated to either of two groups on reaching post-operative recovery.

Group A was administered Injection Pheniramine 22.75 mg IV.

Group B was administered Injection Hyoscine 20 mg IV.

Both drugs were diluted with normal saline to make a total volume of 10 ml in identical syringes.

Randomization was done by computer generated random numbers which were kept in an opaque sealed envelope. A number inside the envelope determined the group to which the patient belonged. The

envelope was opened and study medication prepared by another anaesthesia resident, not involved with the study.

Follow up of patients was done by an anaesthesia resident blinded to the study drugs administered. At each observation interval, post-operative pain as assessed by NRS, Heart rate (HR), Mean blood pressure (MAP), NRS score for CRBD and sedation score of patient was also recorded. The follow up assessment was performed at 30 min, 1 hours and every subsequent hour for 6 hours. During each evaluation, the patient was also asked to determine whether the pain was related to CRBD or to the wound of surgery. Any patient complaining of pain, or reporting NRS ≥4 for pain at surgical site or demanding an analgesic was administered fentanyl 50 mcg IV. The time of administration of rescue analgesic and NRS at that time were recorded. Patients still complaining of CRBD grade 2 or 3 at subsequent observation intervals were managed with rescue dose of tramadol 50 mg, which was recorded.

Sedation was evaluated using a modified Observer's Assessment of Alertness/Sedation score (given below) at the each observation time interval.

All patients were continuously monitored and any episode of bradycardia (defined as Heart rate < 60/ min) or tachycardia (defined as Heart rate > 100/ min) were noted.

Any episode of hypotension defined as (MAP below 20 % of pre-anaesthetic levels) or hypertension (MAP above 20 % of pre-anaesthetic levels) was also recorded. These problems were managed by anaesthesiologist who conducted the case as per department protocol.

OUTCOME

PRIMARY OUTCOME

The primary outcome was measured as reduction in severity of CRBD.

SECONDARY OUTCOME

The secondary outcome was measured as dose and frequency of post-operative analgesic (tramadol) used and adverse effects.

STATISTICAL ANALYSIS

The objective of the study was to compare the efficacy of Pheniramine and Hyoscine in post-operative management of CRBD after general anaesthesia.

The formula used was as under:

$n = (\sigma 12 + \sigma 22)\ (Z\alpha + Z\beta)2/(\ m1 - m2)2$

Where,

$Z\alpha$ = Value of standard normal variate corresponding to α level of significance (1.96)

$Z\beta$ = the standard normal deviate for desired power (1.282)

m = Average

σ = Standard deviation

Assumptions:

From the pilot study conducted on 10 subjects and using NRS as assessment tool for CRBD, Mean NRS at 2 hours in group A came out to be 4 ± 1.2 while in Group 2 it was 5.5 ± 2.1.From this study the sample size for 95% confidence level & 90% power worked out to be 27 in each group .Assuming 10% drop out, we included 30 cases in each group.

OBSERVATIONS AND RESULTS

The present study was conducted in a randomized, double blinded manner in the Department of Anaesthesiology, Dayanand Medical College and Hospital on a total of 60 adult male patients aged 25-55 years belonging to ASA grade I and II posted for elective non-urological surgeries under general anaesthesia.

The study aimed to compare Pheniramine versus Hyoscine for management of post-operative CRBD after general anaesthesia. Patients who complained of CRBD grade 2 or 3 were enrolled for the study and randomly allocated to either of two groups on reaching post-operative recovery.

Group A was administered Injection Pheniramine 22.75 mg IV.

Group B was administered Injection Hyoscine 20 mg IV.

Both drugs were diluted with normal saline to make a total volume of 10 ml in identical syringes.

The observations of our comparative study are as follows:

DEMOGRAPHIC PROFILE

TABLE 1: Mean age distribution

	Group A		Group B		t	p-value
	Mean	SD	Mean	SD		
Age(Years)	36.93	9.82	41.37	9.74	1.756	0.084

Mean age of patients in group A was 36.93(±9.82) years and in group B was 41.37(±9.74) years. There was no statistically significant difference among the two groups with respect to age, p value being 0.084(Table 1, Figure 1).

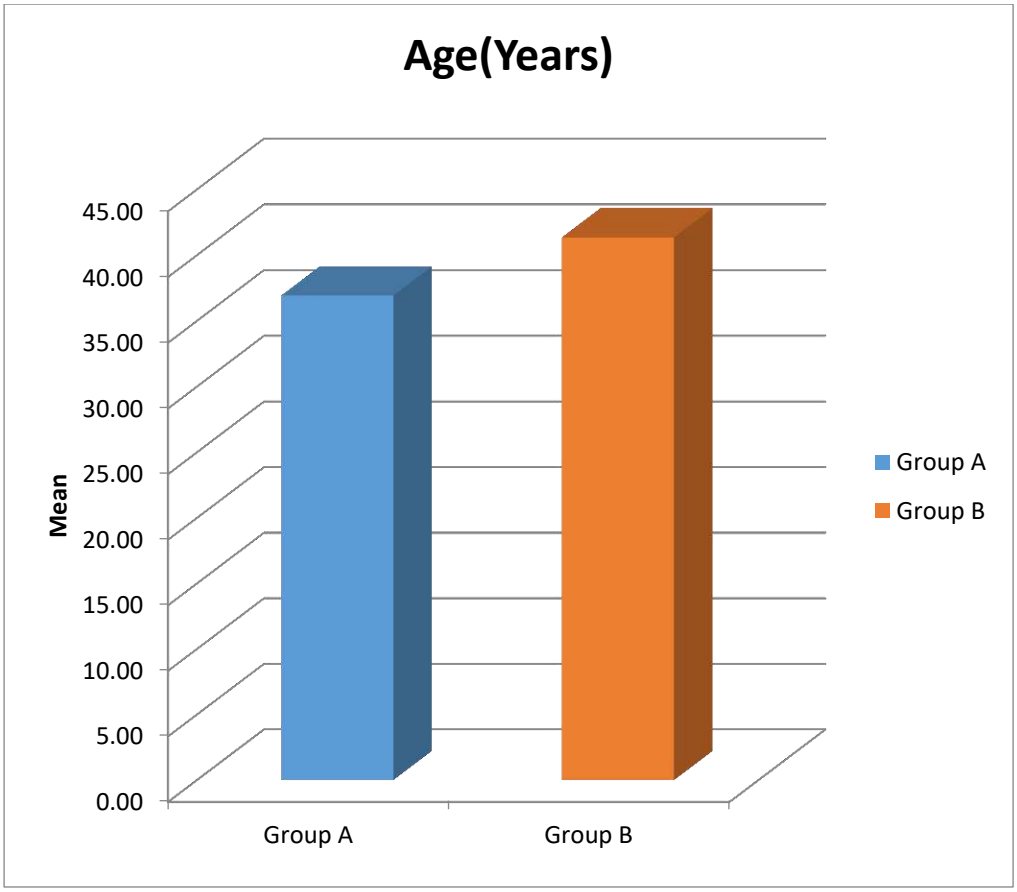

Figure 1: Mean age distribution

TABLE 2: Mean height

	Group A		Group B		t	p-value
	Mean	SD	Mean	SD		
Height(cm)	166.75	11.28	168.99	10.39	0.802	0.426

Mean height of patients in group A was 166.75(±11.28) centimetres and in group B was 168.99(±10.39) centimetres. There was no statistically significant difference among the two groups with respect to height, p value being 0.426(Table 2, Figure 2).

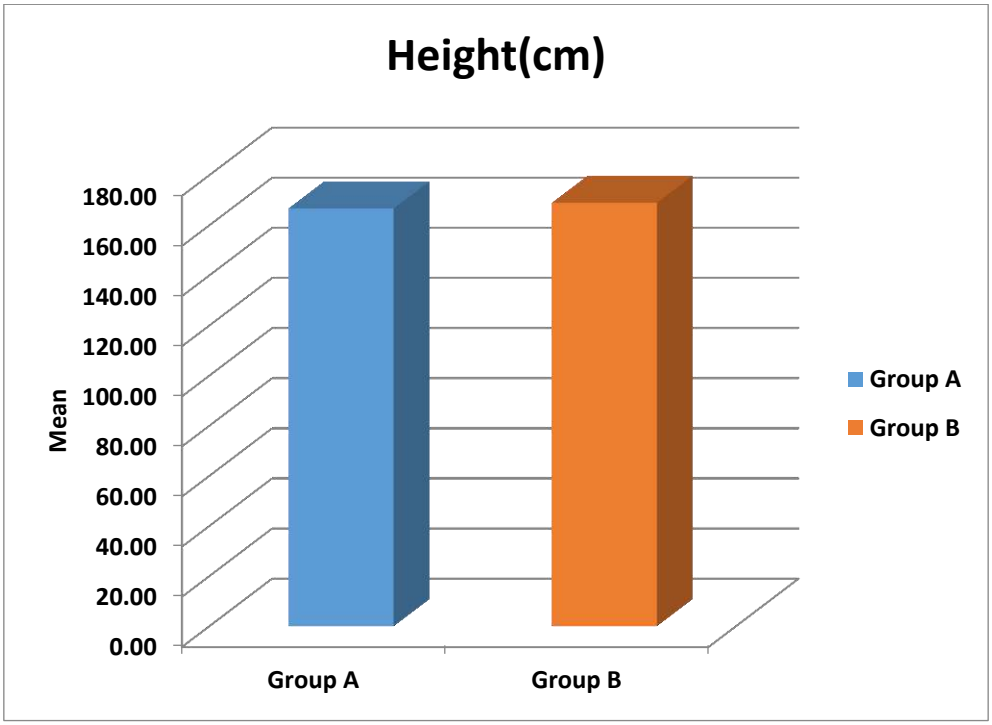

Figure 2: Mean height

TABLE 3: Mean weight

	Group A		Group B		t	p-value
	Mean	SD	Mean	SD		
Weight(kg)	84.17	7.68	81.03	10.80	-1.295	0.201

Mean weight of patients in group A was 84.17(±7.68) kilograms and in group B was 81.03(±10.80) kilograms. There was no statistically significant difference among the two groups with respect to weight, p value being 0.201(Table 3, Figure 3).

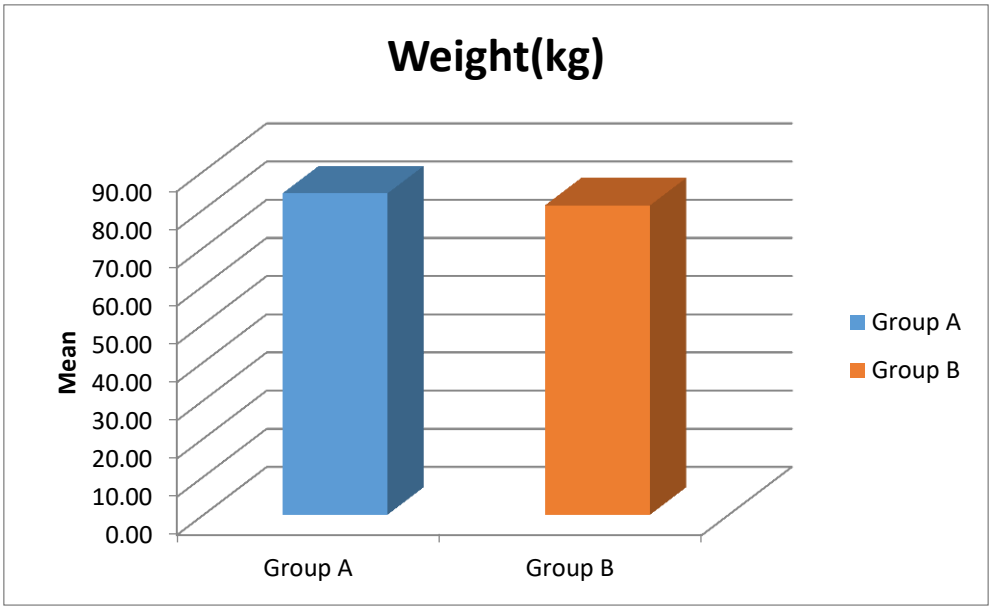

Figure 3: Mean weight

TABLE 4: Mean BMI

	Group A		Group B		t	p-value
	Mean	SD	Mean	SD		
BMI(kg/m2)	27.21	1.65	26.49	2.52	-1.309	0.196

Mean BMI of patients in group A was 27.21(±1.65) kg/m2 and in group B was 26.49(±2.52) kg/m2. There was no statistically significant difference among the two groups with respect to BMI, p value being 0.196(Table 4, Figure 4).

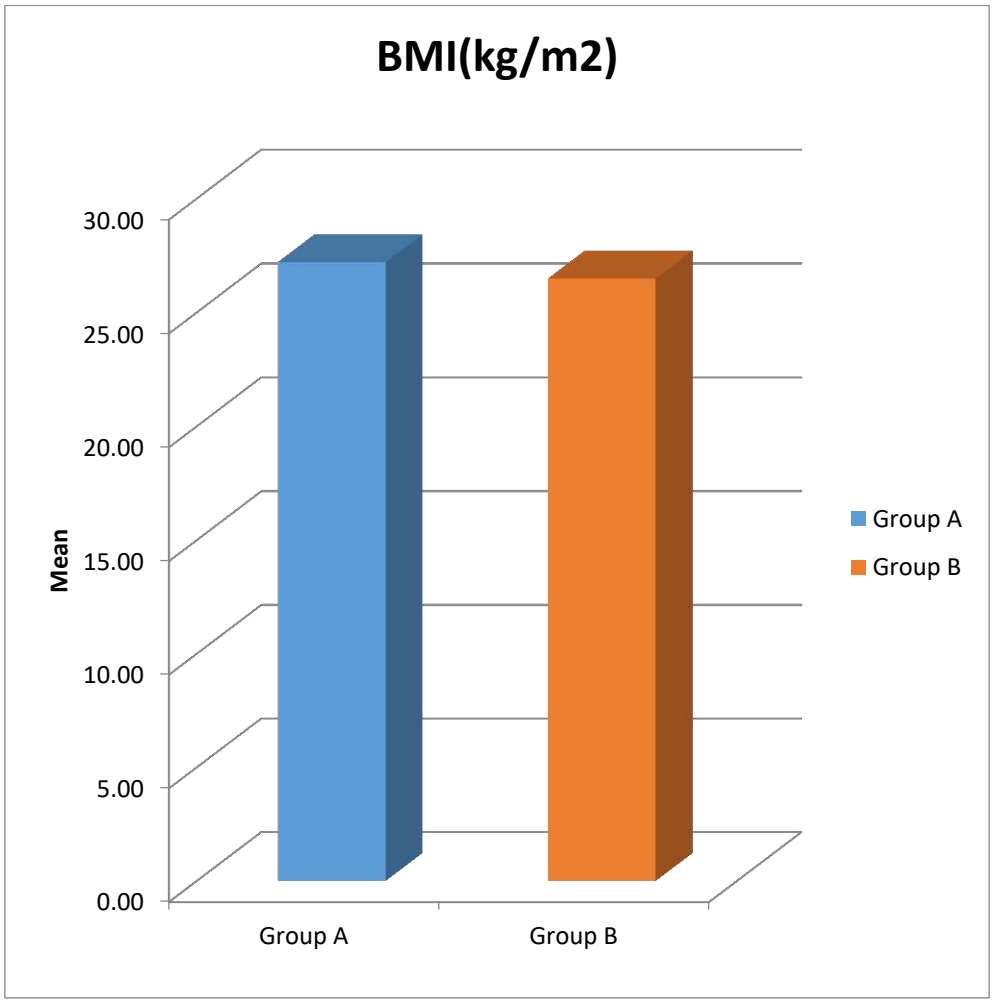

Figure 4: Mean BMI

TABLE 5: ASA physical status

		Group A		Group B		Total	Chi-square value	p-value
		No. of cases	%age	No. of cases	%age			
ASA	1	15	50.0%	15	50.0%	30	0.000	1.000
	2	15	50.0%	15	50.0%	30		
Total		30	100.0%	30	100.0%	60		

50 % patients in both the groups belonged to ASA physical status 1 and 50 % patients in both the groups belonged to ASA physical status 2. The difference in ASA distribution was statistically not significant. (p value 1.00)(Table 5, Figure 5)

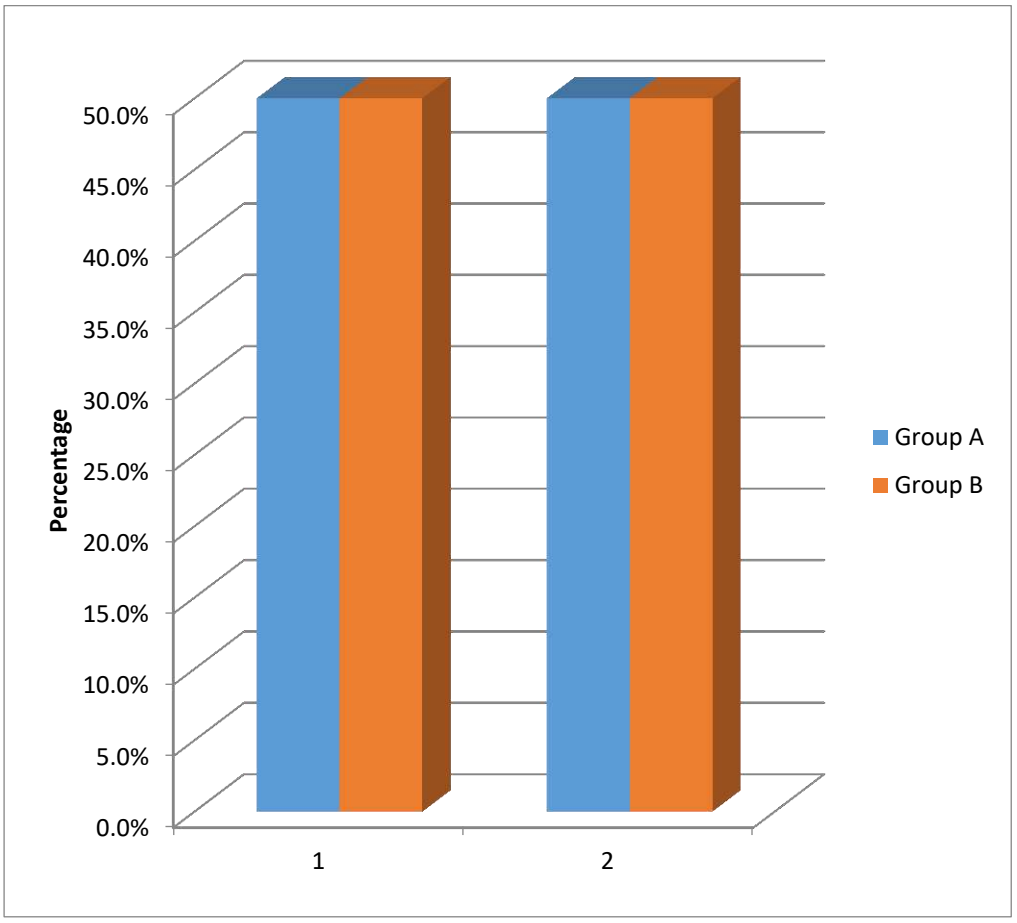

Figure 5: ASA physical status

TABLE 6: Grade of CRBD After shifting to PACU

	Group A		Group B		Z	p-value
Grade of CRBD After shifting to PACU	Mean	SD	Mean	SD		
Grade of CRBD_(0min)	0.07	0.25	0.07	0.25	0.000	1.000
Grade of CRBD_30 min	1.43	0.90	1.13	0.78	-1.385	0.171
Grade of CRBD_1 hour	1.90	1.03	2.03	0.72	0.582	0.563
Grade of CRBD_2hours	1.13	0.82	1.80	0.61	3.574	0.001
Grade of CRBD_3 hours	0.50	0.94	1.40	0.72	4.161	0.001
Grade of CRBD_4 hours	0.27	0.64	1.00	0.79	3.958	0.001
Grade of CRBD_5 hours	0.10	0.31	0.53	0.57	3.664	0.001
Grade of CRBD_6 hours	0.00	0.00	0.03	0.18	1.000	0.321

The mean grade of CRBD on shifting to PACU (0 min) for both the groups was 0.07 $\pm$0.25 and the difference was statistically not significant with p value being 1.000.

The mean grade of CRBD at 30 min after shifting to PACU for Group A was 1.43 $\pm$0.90 and for Group B was 1.13 $\pm$0.78 and this difference again was statistically not significant with p value being 0.171.

Similarly the mean grade of CRBD after shifting to PACU at 1hr for Group A was 1.90 $\pm$1.03 and for Group B was 2.03 $\pm$0.72 and was statistically not significant with p value being 0.563.

Thereafter at 2hour, 3 hour, 4 hour and 5 hours interval, the difference in the mean grade of CRBD was highly significant with p values being 0.001 at each interval.

At 6 hour interval, the difference between the mean grade of CRBD again became statistically insignificant with p value 0.321. (Table 6, Figure 6)

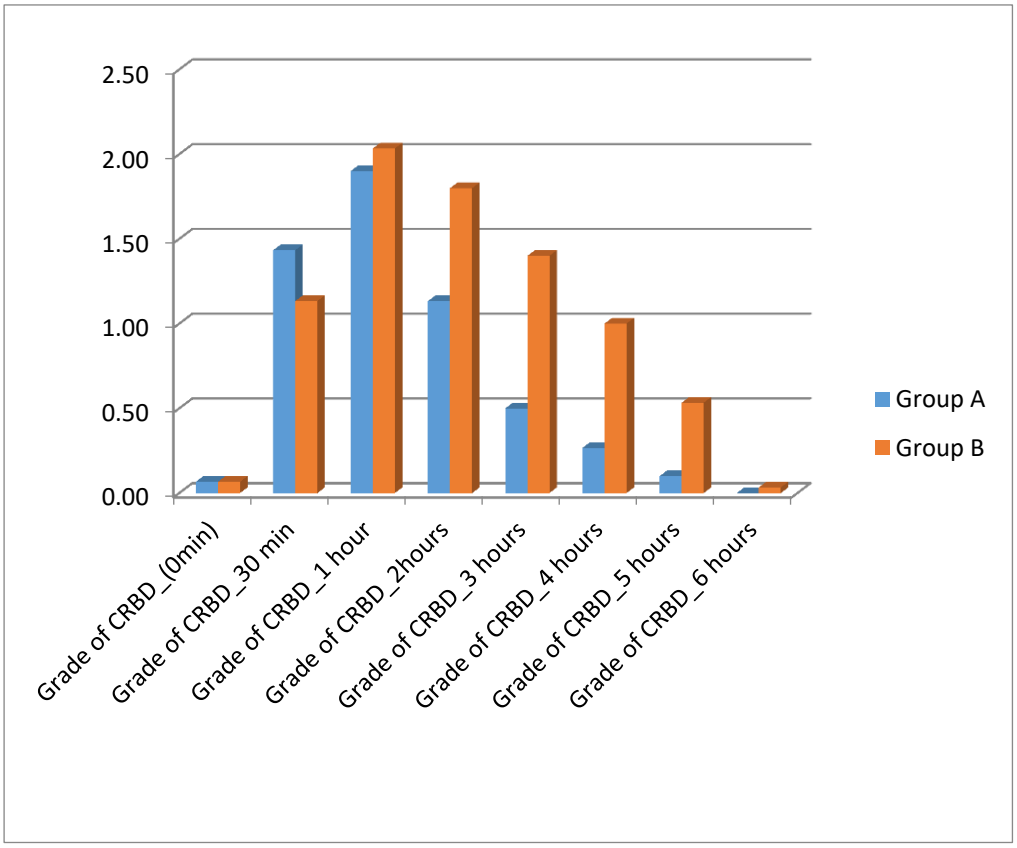

Figure 6: Grade of CRBD after shifting to PACU

TABLE 7: Mean time of administration of treatment for CRBD (min)

	Group A		Group B		Z	p-value
	Mean	SD	Mean	SD		
Mean Time of administration of treatment for CRBD(min)	65.00	42.49	63.00	32.82	-0.457	0.648

Mean time for administration of study drug for CRBD in group A was 65.00(±42.49) min and in group B was 63.00(±32.82) min. There was no statistically significant difference among the two groups with respect to mean time of administration of study drug for CRBD, p value being 0.648(Table 7, Figure 7).

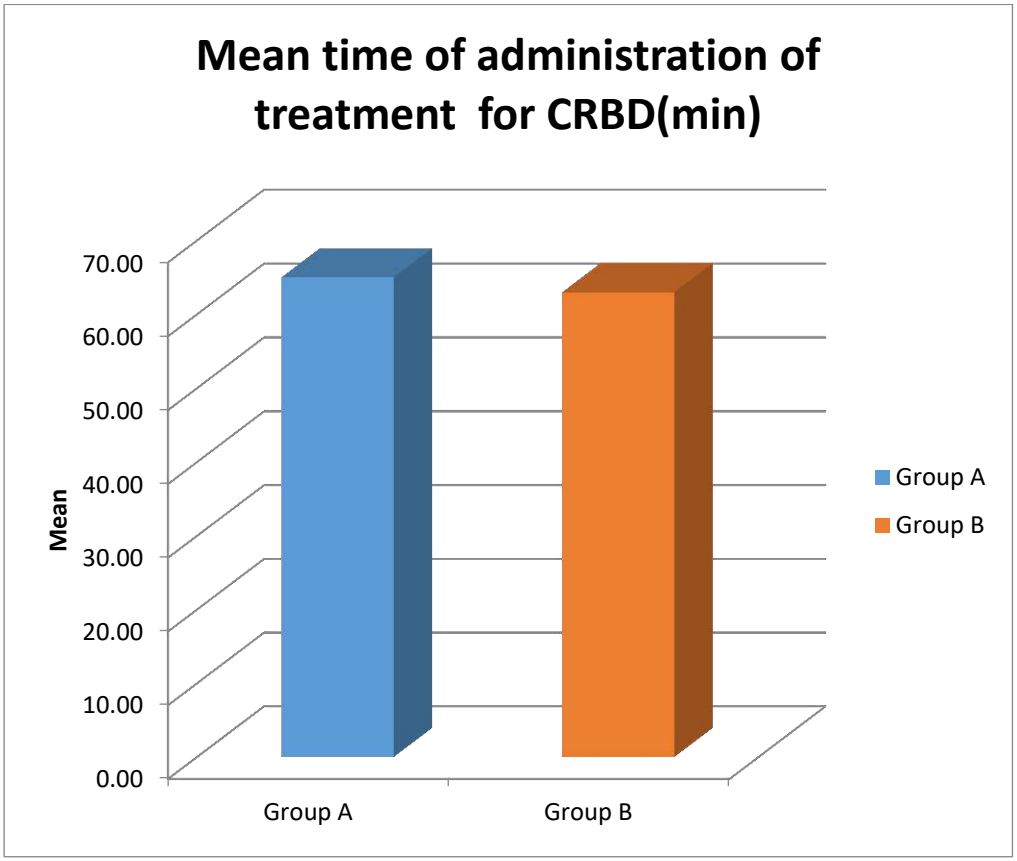

Figure 7: Mean time of administration of Treatment for CRBD (min)

TABLE 8: NRS for Pain related to CRBD after shifting to PACU

	Group A		Group B			
NRS for pain related to CRBD After shifting to PACU	Mean	SD	Mean	SD	Z	p-value
(0min)	0.20	0.55	0.20	0.55	0.000	1.000
30 min	3.10	2.14	2.53	1.78	-0.907	0.365
1 hour	4.13	2.10	4.33	1.77	-0.263	0.792
2hours	2.57	1.57	4.10	1.52	-3.534	0.001
3 hours	1.47	1.98	3.33	1.58	-4.099	0.001
4 hours	0.67	1.37	2.10	1.54	-3.707	0.001
5 hours	0.27	0.64	1.10	0.92	-3.905	0.001
6 hours	0.00	0.00	0.07	0.37	-1.000	0.317

The mean NRS for pain related to CRBD on shifting to PACU (0 min) for both the groups was 0.20 $\pm$0.55 and the difference was statistically not significant with p value being 1.000.

The mean NRS for pain related to CRBD at 30 min after shifting to PACU for Group A was 3.10 $\pm$2.14 and for Group B was 2.53 $\pm$1.78 and this difference again was statistically not significant with p value being 0.365.

Similarly the mean NRS for pain related to CRBD after shifting to PACU at 1hr for Group A was 4.13 $\pm$2.10 and for Group B was 4.33 $\pm$1.77 and was statistically not significant with p value being 0.792.

Thereafter at 2hour, 3 hour, 4 hour and 5 hours interval, the difference in the mean NRS for pain related to CRBD was highly significant with p values being 0.001 at each interval.

At 6 hour interval, the difference between the mean NRS for pain related to CRBD again became statistically insignificant with p value 0.317. (Table 8, Figure 8)

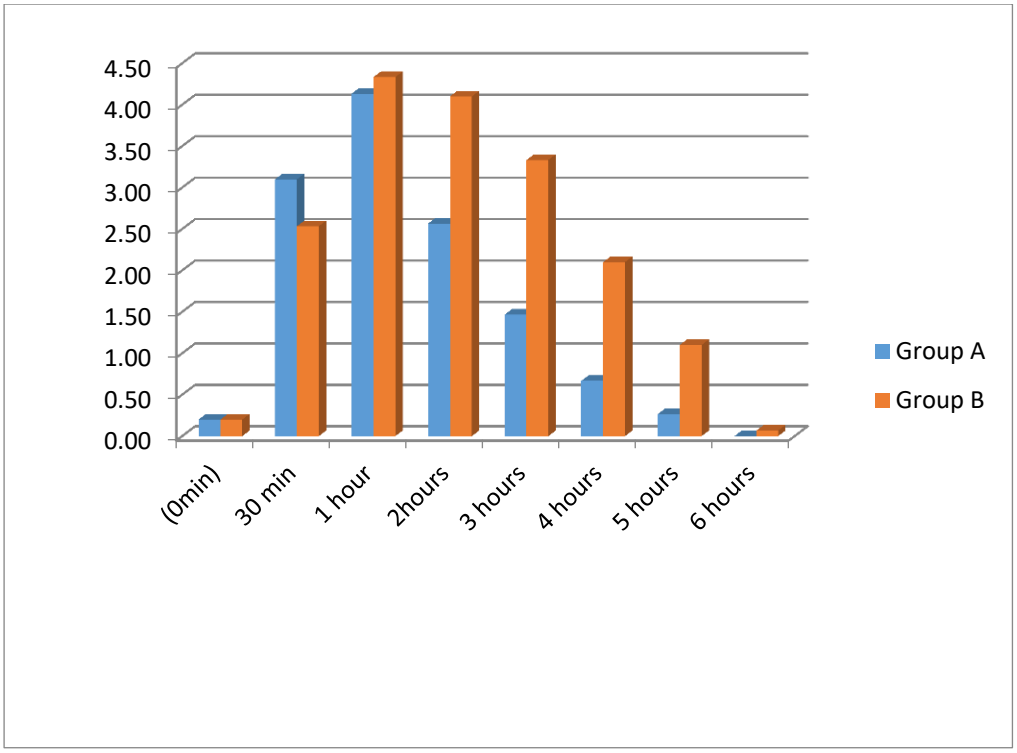

Figure 8: NRS for pain related to CRBD after shifting to PACU

TABLE 9: Time taken for resolution of CRBD (min)

	Group A		Group B		Z	p-value
	Mean	SD	Mean	SD		
Time taken for resolution of CRBD(min)	80.00	43.39	145.00	76.01	-3.512	0.001

Time taken for CRBD to resolve in Group A was 80± 43.39 min and in Group B it was 145± 76.01 min and this difference was statistically significant with p value being 0.001 (Table 9, Figure 9).

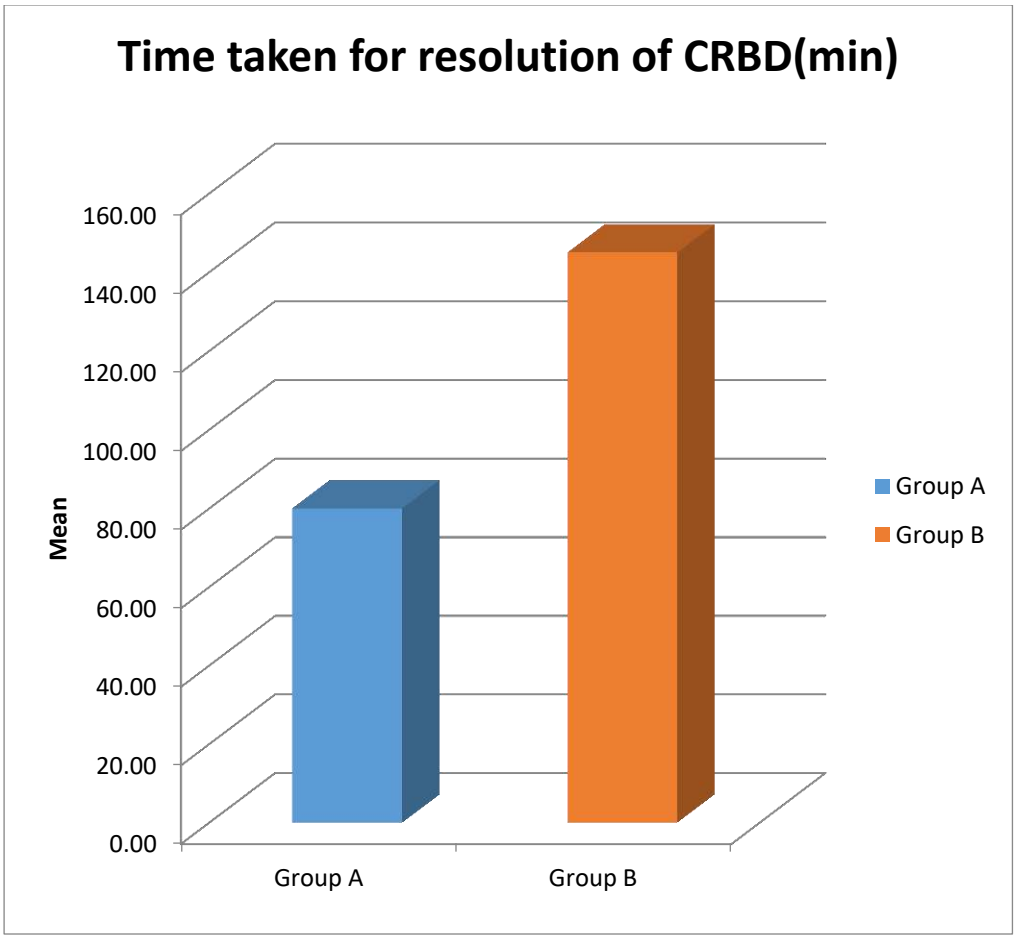

FIGURE 9: Time taken for resolution of CRBD (min)

TABLE 10: Rescue dose of Tramadol administration (mg)

	Group A		Group B		Z	p-value
	Mean	SD	Mean	SD		
Rescue dose of Tramadol for CRBD(mg)	5.00	15.26	48.33	40.44	-4.585	0.001

In Group A, patients required less mean rescue dose of Tramadol (mg) for CRBD (5.00±15.26) while in Group B requirement of mean rescue dose of Tramadol (mg) was higher (48.33±40.44). This difference in requirement of tramadol was statistically significant with p value being 0.001(Table 10, Figure 10).

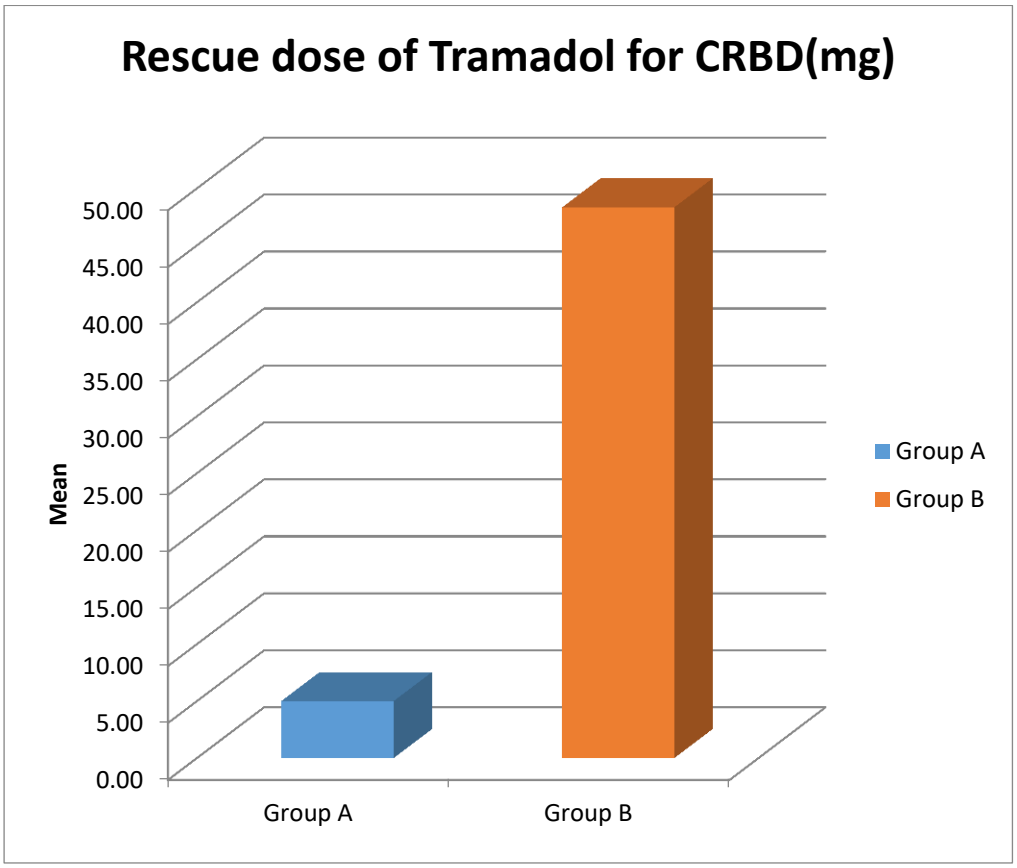

FIGURE 10: Rescue dose of Tramadol administration for CRBD (mg)

TABLE 11: Mean time of Tramadol administration (min)

	Group A		Group B		Z	p-value
	Mean	SD	Mean	SD		
Mean time of Tramadol administration (min)	240.00	0.00	147.00	36.29	-4.352	0.001

In Group B patients required tramadol (147.00±36.29)min as rescue drug for CRBD earlier than in Group A (240.00±0.00)min.This difference in mean time of tramadol was statistically significant with p value being 0.001(Table 11, Figure 11).

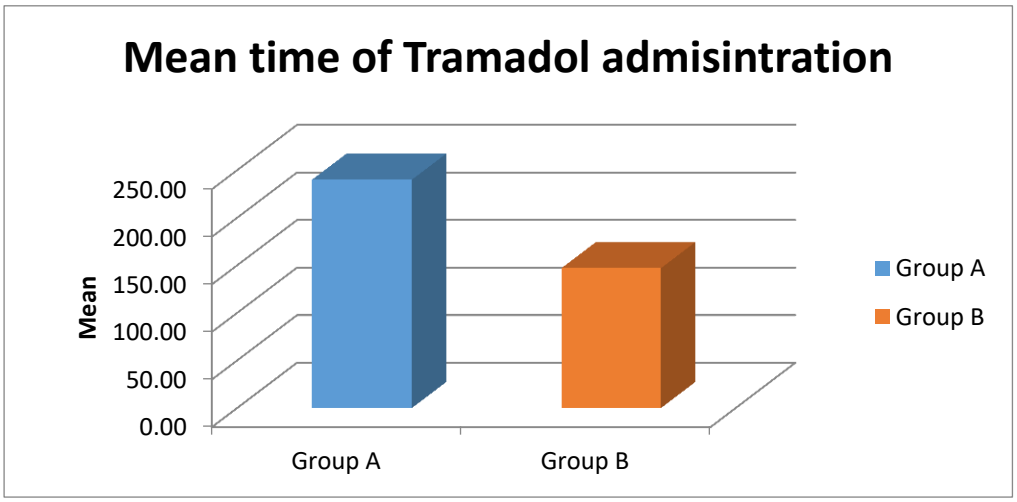

Figure 11: Mean time of Tramadol administration (min)

TABLE 12: Frequency of Tramadol administration

		Group A		Group B		Total	Chi-square value	p-value
		No. of cases	%age	No. of cases	%age			
Frequency of Tramadol administration	0	27	90.0%	10	33.3%	37	21.382	0.001
	1	3	10.0%	11	36.7%	14		
	2	0	0.0%	9	30.0%	9		
Total		30	100.0%	30	100.0%	60		

In Group A 27 out of 30 patients (90%) did not require rescue tramadol administration, while only 3 patient's required tramadol once. On the other hand in Group B, 10 out of 30 patients (33.3%) did not require tramadol administration. 11 patients required tramadol administration once (36.7%) and 9 patients required it twice (30%). Hence difference between frequencies of rescue tramadol administration was statistically significant between both groups with p value being 0.001. (Table 12, Figure 12).

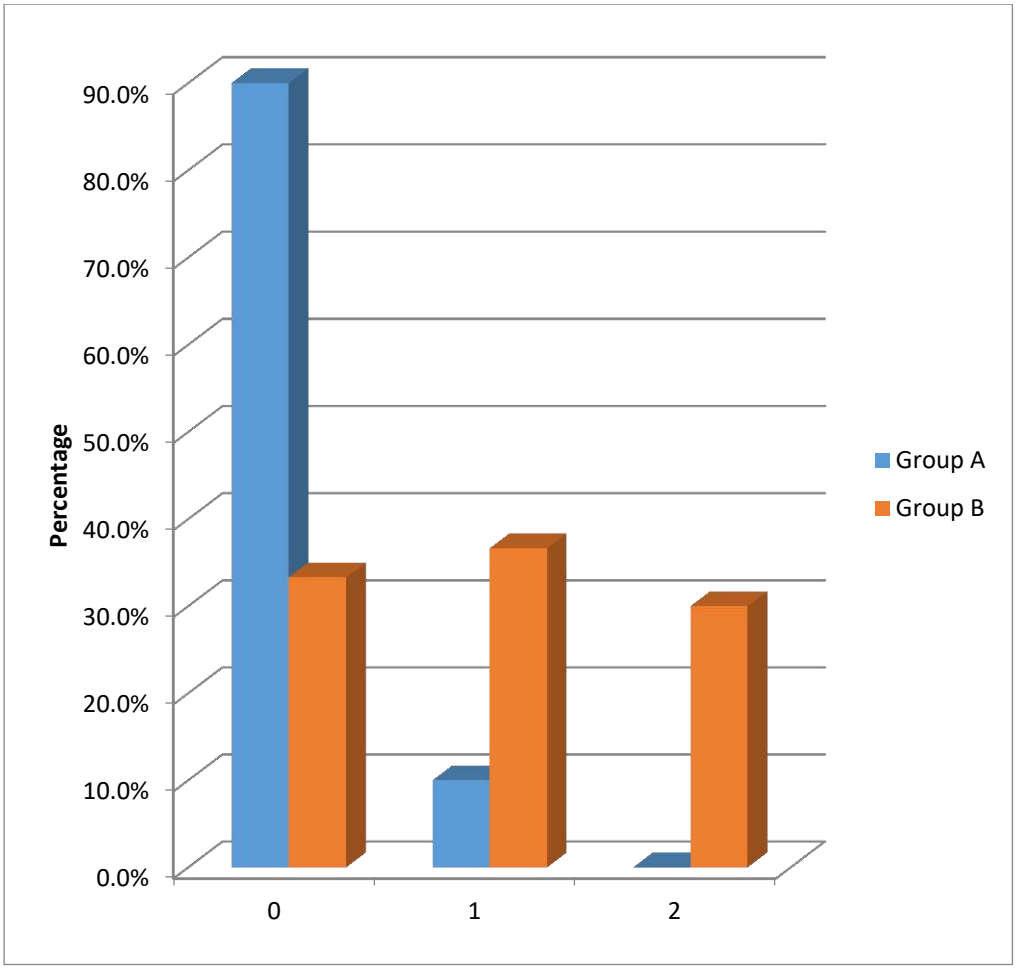

Figure 12: Frequency of Tramadol administration

TABLE 13: NRS for Pain at surgical site after shifting to PACU

	Group A		Group B		Z	p-value
NRS for pain at surgical site	Mean	SD	Mean	SD		
NRS_ After shifting to PACU (0min)	0.13	0.43	0.20	0.55	-0.425	0.671
NRS_ 30 min	0.67	1.09	1.00	1.02	-1.561	0.118
NRS_ 1 hour	0.77	1.43	2.20	2.01	-3.003	0.003
NRS_ 2 hours	0.80	1.47	2.63	2.22	-3.305	0.001
NRS_ 3 hours	0.60	1.25	2.37	2.24	-3.518	0.001
NRS_ 4 hours	0.37	0.72	1.23	1.28	-3.109	0.002
NRS_ 5 hours	0.30	0.79	0.40	0.67	-0.938	0.348
NRS_ 6 hours	0.10	0.31	0.07	0.37	-0.975	0.330

The mean NRS for pain at surgical site on shifting to PACU (0 min) and after 30 min for Group A was 0.13$\pm$0.43 and 0.67$\pm$1.09. Similarly for Group B it was 0.20 $\pm$0.55 and 1.00 $\pm$1.02. The difference between both groups was statistically not significant with p value being 0.671 and 0.118.

Thereafter at 1 hour, 2hour, 3 hour and 4 hours interval, the difference in the mean NRS for pain at surgical site was highly significant with p values being 0.003, 0.001, 0.001 and 0.002 respectively at each interval.

Afterwards at 5 and 6 hour interval, the difference between the mean NRS for pain at surgical site again became statistically insignificant with p value 0.348 and 0.330. (Table 13, Figure 13)

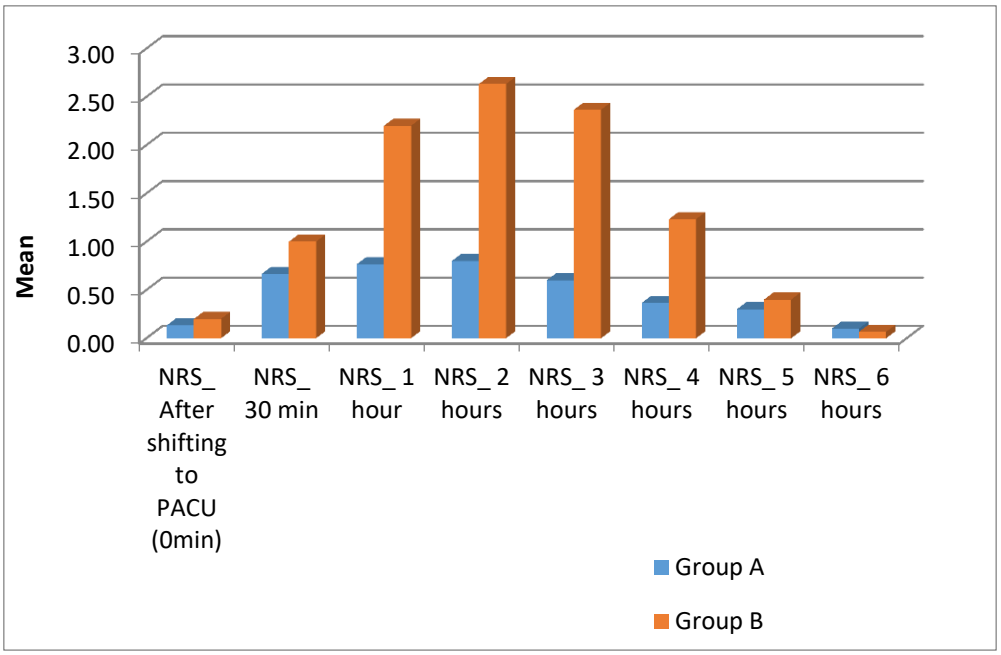

Figure 13: NRS for Pain at surgical site after shifting to PACU

TABLE 14: Rescue dose of Fentanyl administration (mcg)

	Group A		Group B		Z	p-value
	Mean	SD	Mean	SD		
RESCUE DOSE OF FENTANYL ADMINISTERED(mcg)	8.33	18.95	35.00	32.56	-3.508	0.001

In Group A, patients required less mean rescue dose of Fentanyl (mcg) for pain related to surgical site (8.33±18.95) while in Group B requirement of mean rescue dose of Fentanyl (mcg) was higher (35.00±32.56). This difference in requirement of Fentanyl was statistically significant with p value being 0.001(Table 14, Figure 14).

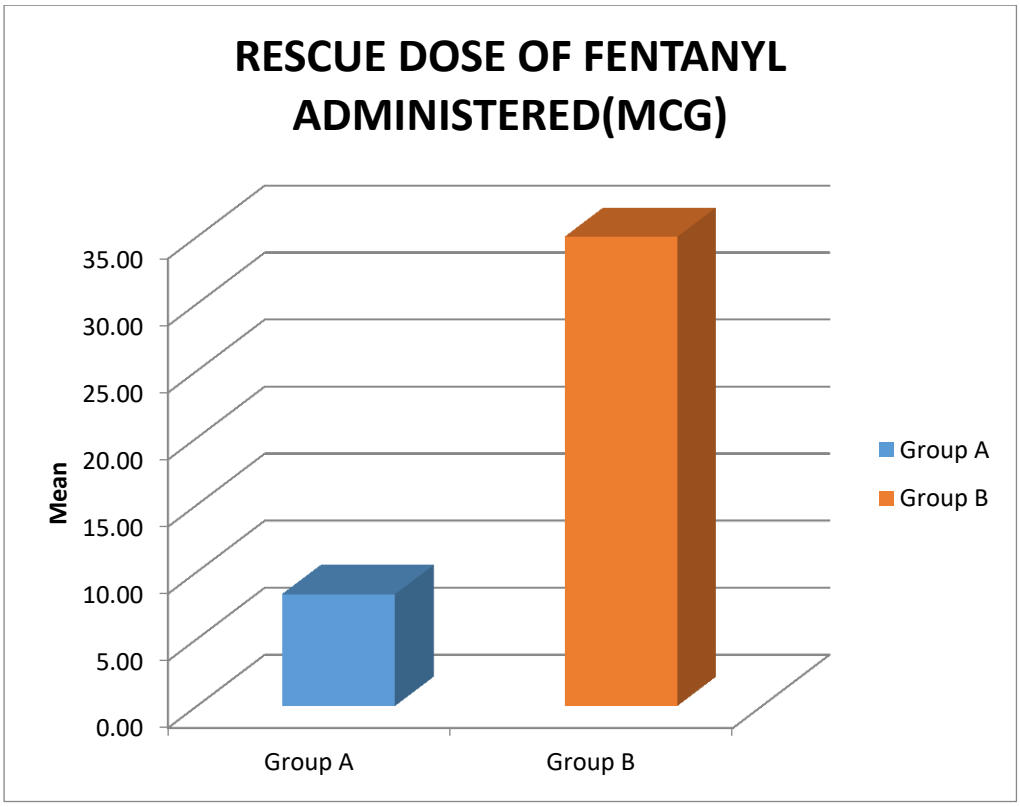

Figure 14: Rescue dose of Fentanyl administration (mcg)

TABLE 15: Mean time of Fentanyl administration (min)

	Group A		Group B		Z	p-value
	Mean	SD	Mean	SD		
Mean Time of Fentanyl administration (min)	156.00	90.99	126.67	49.94	-0.968	0.344

In Group B, patients required fentanyl (126.67±49.94)min as rescue drug for surgical site pain earlier than in Group A (156.00±90.99)min.This difference in mean time of fentanyl administration was not statistically significant with p value being 0.344(Table 15, Figure 15)

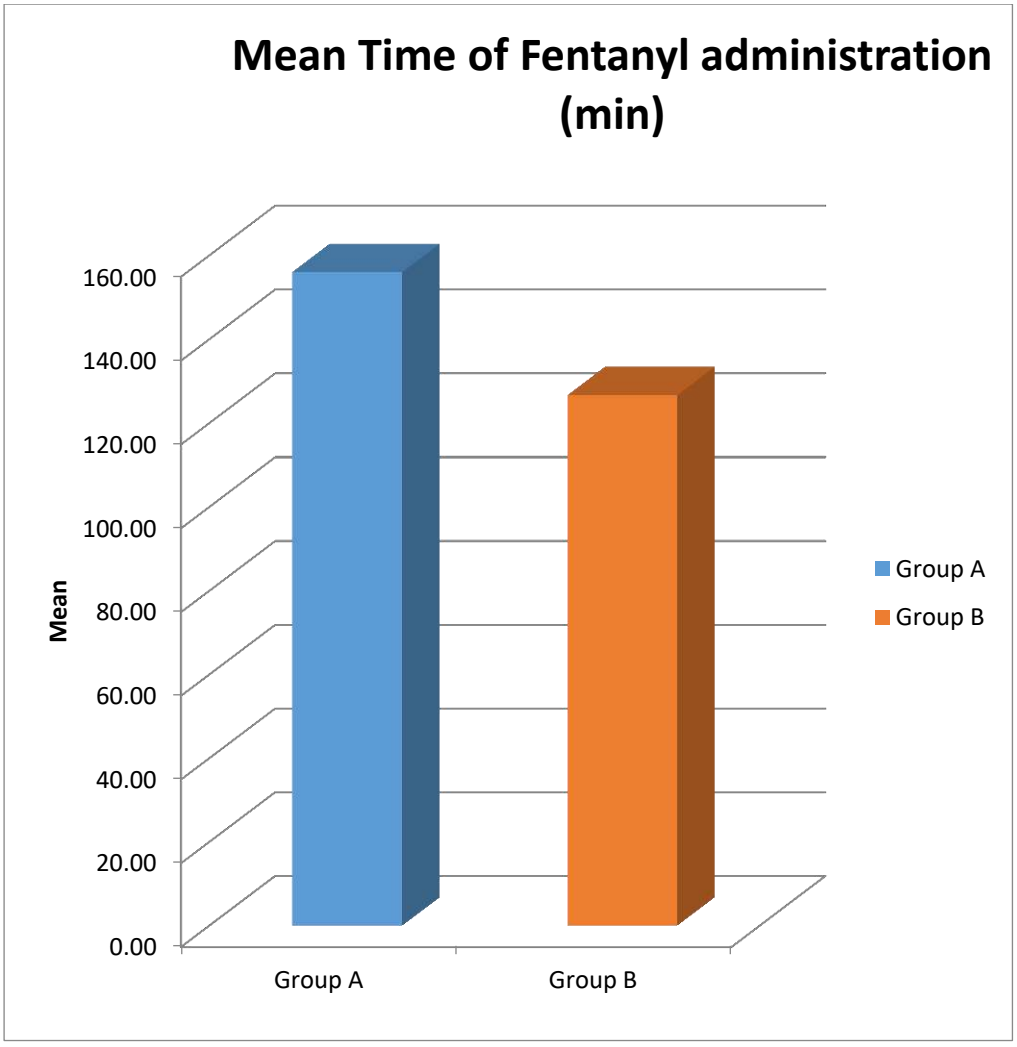

Figure 15: Mean time of Fentanyl administration (min)

TABLE 16: Sedation Score

	Group A		Group B		t	p-value
	Mean	SD	Mean	SD		
SEDATION SCORE After shifting to PACU(0min)	4.97	0.32	5.00	0.00	-0.587	0.557
SEDATION SCORE_30 min	5.67	0.61	5.43	0.50	-2.021	0.043
SEDATION SCORE_1 hour	5.53	0.63	5.73	0.52	-1.381	0.167
SEDATION SCORE_2 hours	4.77	0.68	5.50	0.51	-3.999	0.001
SEDATION SCORE_3 hours	4.37	0.93	4.97	0.72	-2.640	0.008
SEDATION SCORE_4 hours	4.57	0.94	4.90	0.55	-1.441	0.150
SEDATION SCORE_5 hours	4.63	0.81	4.83	0.38	-0.617	0.537
SEDATION SCORE_6 hours	4.80	0.41	4.90	0.31	1.077	0.286

The mean sedation score after shifting to PACU at 0 min and 30 min and 1 hour for Group A was 4.97 $\pm$0.32 , 5.67 $\pm$0.61 and 5.53 $\pm$0.63 for Group B was 5 $\pm$0.00 ,5.43 $\pm$0.50 and 5. 73 $\pm$0.52 .This difference was statistically not significant with p value being 0.557, 0.043 and 0.167 respectively.

Thereafter at 2hr, 3hr the difference between mean sedation score became statistically significant with p value being 0.001, and 0.008 at 2hr, 3hr respectively.

After that at 4hr, 5hr and 6 hr this again became statistically insignificant with p value being 0.150, 0.537and0.286 respectively (Table 16, Figure 16)

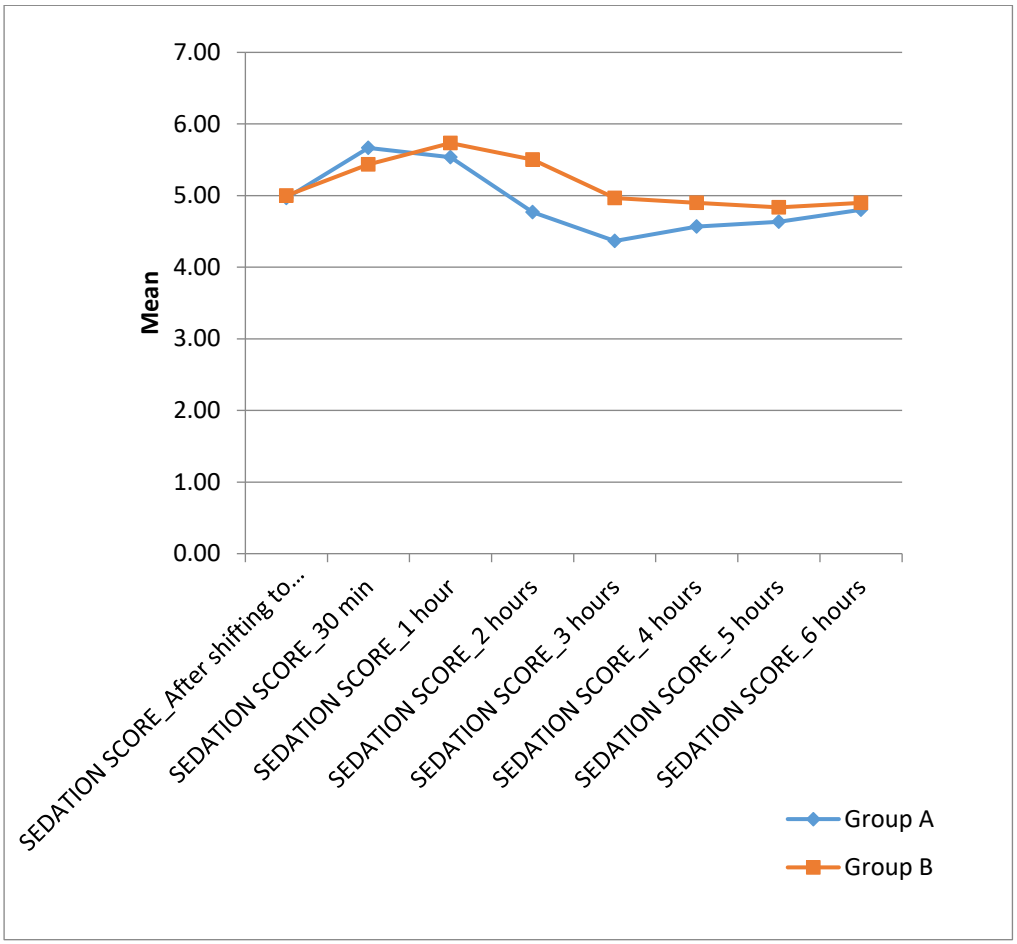

FIGURE 16: Sedation Score

Table 17: Urine output (ml)

	Group A		Group B		Z	p-value
	Mean	SD	Mean	SD		
URINE OUTPUT After shifting to PACU(0min)	73.50	34.62	58.83	29.64	-1.430	0.153
URINE OUTPUT_30 min	147.50	54.59	128.17	41.99	-1.095	0.273
URINE OUTPUT_1 hour	217.67	67.60	189.50	50.35	-1.275	0.202
URINE OUTPUT_2 hours	279.33	96.24	247.37	75.51	-1.245	0.213
URINE OUTPUT_3 hours	355.00	100.58	320.00	96.88	-1.216	0.224
URINE OUTPUT_4 hours	431.00	115.86	401.33	108.97	-0.911	0.363
URINE OUTPUT_5 hours	503.83	133.01	478.33	125.65	-0.778	0.436
URINE OUTPUT_6 hours	592.67	154.49	561.33	150.94	-0.934	0.350

The mean urine output (ml) after shifting to PACU at 0 min for Group A was 73.50 ±34.62 and for Group B was 58.83 ±29.64 and was statistically not significant with p value being 0.153.

The mean urine output (ml) after shifting to PACU at 30 min for Group A was 147.50 ±54.59 and for Group B was 128.17 ±41.99 and was statistically not significant with p value being 0.273.

There after the mean urine output at each successive interval was statistically not significant with p value being 0.202, 0.213, 0.224, 0.363, 0.436 and 0.350 at 1hr, 2hr, 3hr, 4hr, 5hr and 6hr respectively. (Table 17, Figure 17)

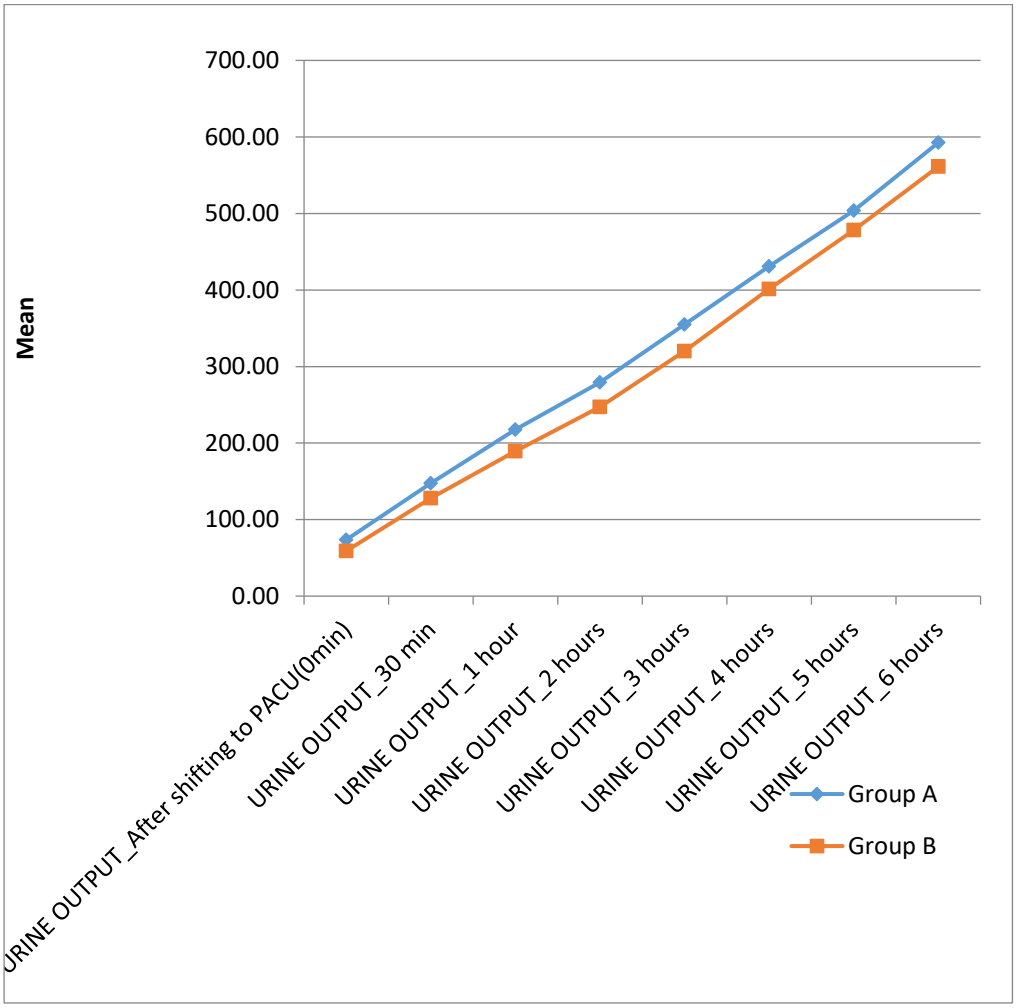

Figure 17: Urine output (ml)

Table 18: Heart Rate (beats/min)

	Group A		Group B		Z	p-value
	Mean	SD	Mean	SD		
HR After shifting to PACU(0min)	74.00	11.01	74.63	8.69	-0.212	0.832
HR_30 min	81.40	17.72	87.47	12.33	-1.042	0.297
HR_1 hour	91.53	14.85	94.63	12.14	-0.967	0.333
HR_2 hours	87.27	12.86	94.30	12.67	-1.852	0.064
HR_3 hours	83.20	14.63	90.27	12.51	-1.794	0.073
HR_4 hours	79.27	12.91	84.97	10.71	-1.585	0.113
HR_5 hours	76.43	11.22	80.93	10.95	-1.114	0.265
HR_6 hours	73.67	9.83	76.13	9.76	-0.689	0.491

The mean heart rate (beats/min) after shifting to PACU at 0 min for Group A was 74.00 $\pm$11.01 and for Group B was 74.63$\pm$8.69 and was statistically not significant with p value being 0.832.

The mean heart rate (beats/min) after shifting to PACU at 30 min for Group A was 81.40 $\pm$17.72 and for Group B was 87.47$\pm$12.33 and was statistically not significant with p value being 0.297.

There after the mean heart rate (beats/min) at each successive interval was statistically not significant with p value being 0.333, 0.064, 0.073, 0.113, 0.265 and 0.491 at 1hr, 2hr, 3hr, 4hr, 5hr and 6hr respectively. (Table 18, Figure 18)

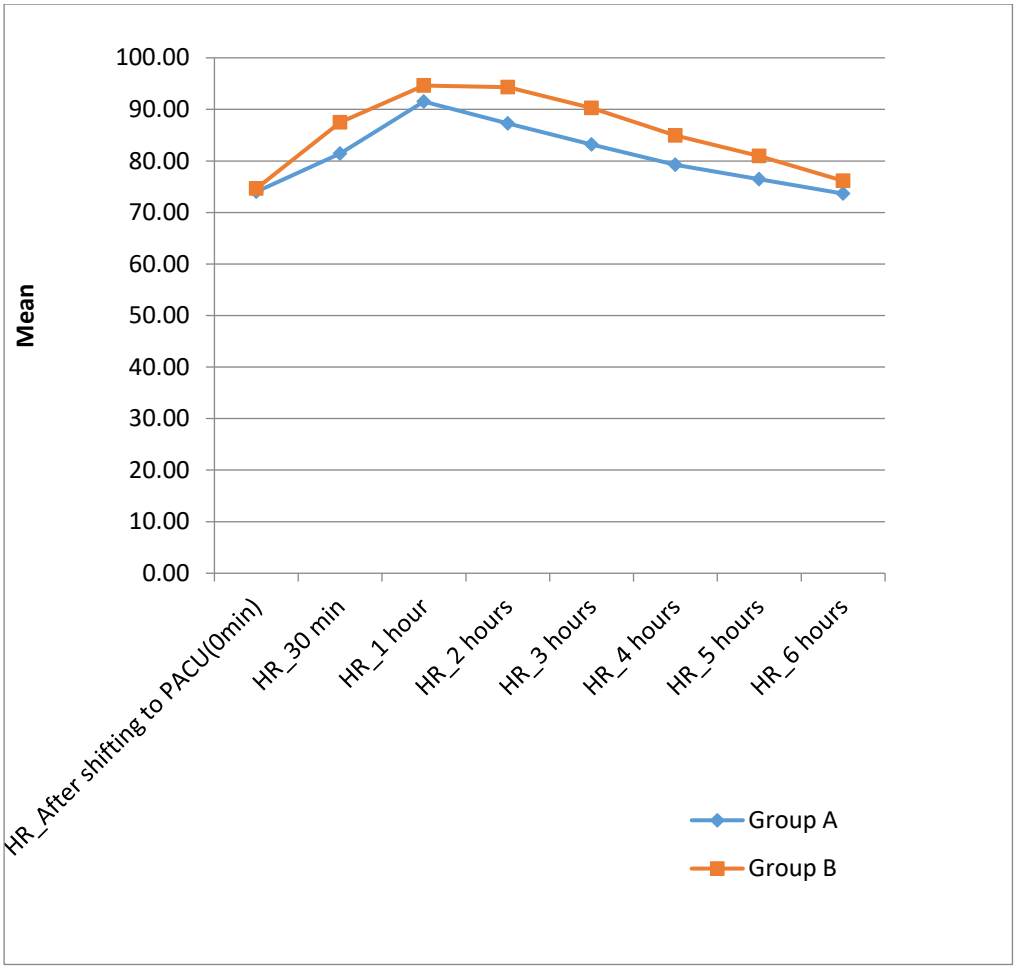

Figure 18: Heart Rate (beats/min)

Table 19: Systolic Blood Pressure (mmHg)

	Group A		Group B		Z	p-value
	Mean	SD	Mean	SD		
SBP After shifting to PACU(0min)	115.20	6.68	115.13	7.96	-0.257	0.797
SBP_30 min	127.53	10.42	128.37	11.47	-0.350	0.726
SBP_1 hour	129.97	25.10	135.87	9.58	-1.040	0.298
SBP_2 hours	130.83	10.96	136.97	11.42	-2.066	0.039
SBP_3 hours	125.53	10.45	130.37	9.79	-1.698	0.090
SBP_4 hours	121.87	9.23	126.67	9.60	-2.092	0.036
SBP_5 hours	116.50	7.23	121.33	8.40	-2.273	0.023
SBP_6 hours	112.23	5.95	115.57	7.05	-1.836	0.066

The mean Systolic Blood Pressure (SBP) (mmHg) for CRBD after shifting to PACU at 0 min for Group A was 115.20 ±6.68 and for Group B was 115.13 ±7.96 and was statistically not significant with p value being 0.797.

Similarly at 30 min and 1hr the difference in mean SBP among the two groups was non-significant with p value being 0.726 and 0.298.

The mean Systolic Blood Pressure (SBP) for CRBD after shifting to PACU at 2hr for Group A was 130.83 ±10.96 mmHg and for Group B was 136.97 ±11.42 mmHg and it was statistically significant with p value being 0.039.

There after the mean Systolic Blood Pressure(SBP) for CRBD at 4 hr and 5hr for Group A was 121.87 ±9.23 and 116.50± 7.23 and for Group B it was 126.67 ±9.60 and 121.33± 8.40 and and was statistically significant with p value being 0.036 and0.023.

Subsequently at 6hr it became statistically not significant with p value being 0.066. (Table 19, Figure 19)

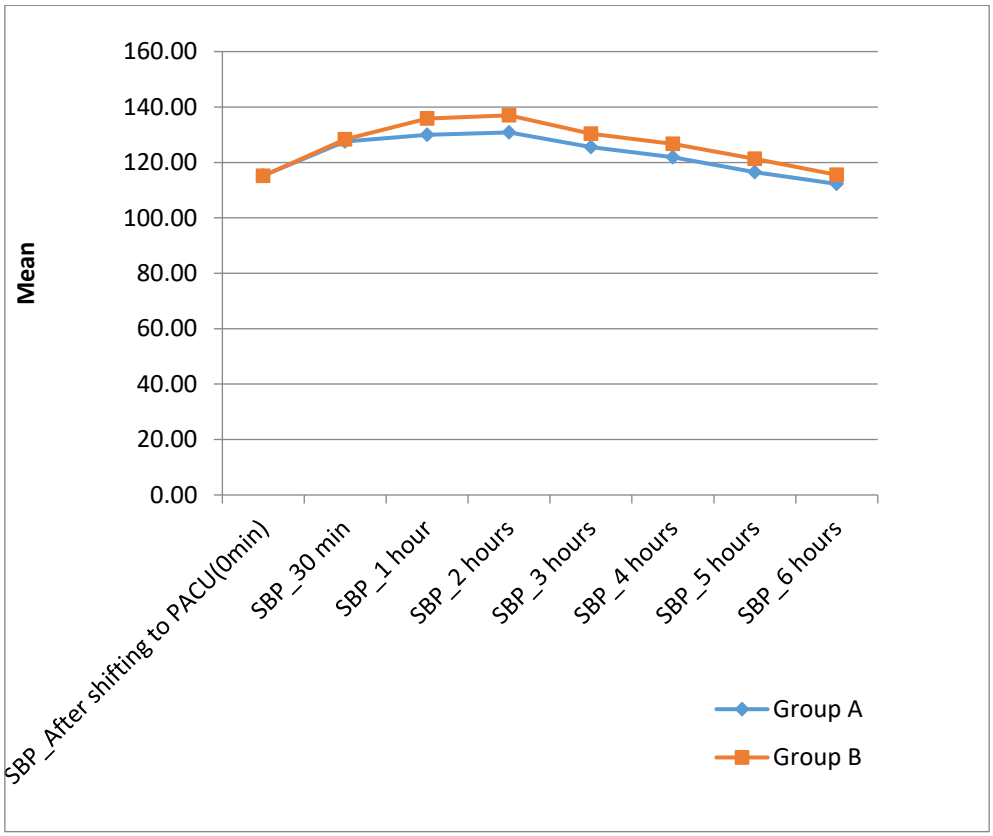

Figure 19: Systolic Blood Pressure (mmHg)

Table 20: Diastolic Blood Pressure (mmHg)

	Group A		Group B		Z	p-value
	Mean	SD	Mean	SD		
DBP After shifting to PACU(0min)	70.40	3.62	71.20	7.38	-0.352	0.725
DBP_30 min	77.90	6.53	75.47	8.76	-1.382	0.167
DBP_1 hour	81.40	9.81	81.03	8.51	-0.149	0.882
DBP_2 hours	76.77	16.19	81.70	8.82	-1.062	0.288
DBP_3 hours	75.47	15.98	79.27	9.86	-0.588	0.557
DBP_4 hours	69.43	19.03	76.93	7.94	-1.379	0.168
DBP_5 hours	71.23	8.01	73.67	7.42	-1.212	0.226
DBP_6 hours	68.00	5.96	67.07	7.86	-0.485	0.628

The mean Diastolic blood pressure (mmHg) after shifting to PACU at all intervals of observations was comparable between both groups and was statistically non- significant. (Table 20, Figure 20)

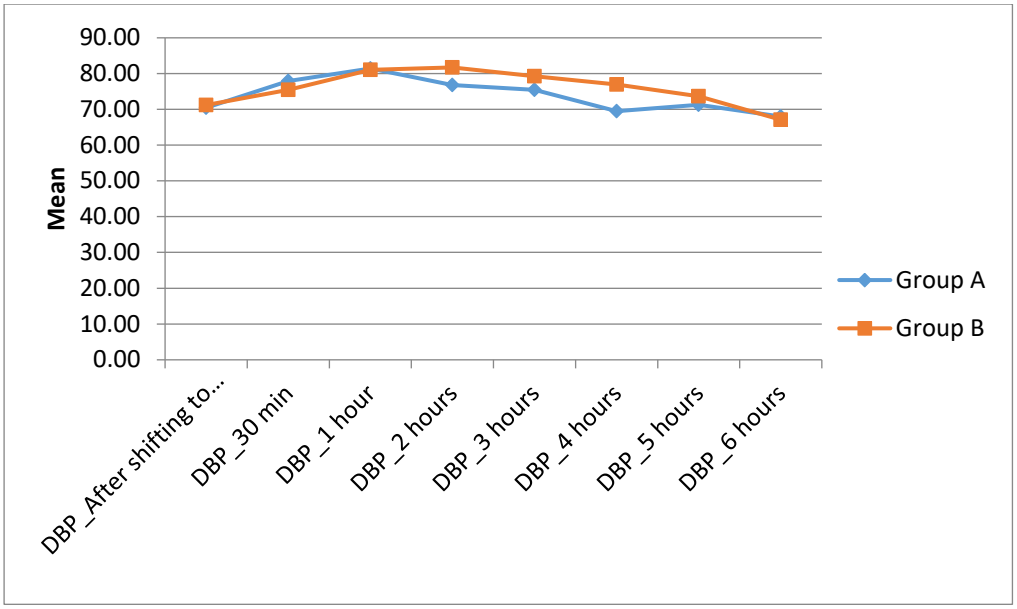

Figure 20: Diastolic Blood Pressure (mmHg)

Table 21: Mean Arterial Pressure (mmHg)

	Group A		Group B		Z	p-value
	Mean	SD	Mean	SD		
MAP After shifting to PACU(0min)	85.20	3.45	85.83	6.96	-0.189	0.850
MAP_30 min	94.50	6.56	93.17	8.09	-0.794	0.427
MAP_1 hour	99.03	9.18	99.30	7.71	-0.148	0.882
MAP_2 hours	96.23	8.74	100.10	8.77	-1.362	0.173
MAP_3 hours	93.73	9.12	96.27	8.87	-0.785	0.432
MAP_4 hours	89.87	7.01	93.57	7.58	-1.792	0.073
MAP_5 hours	86.30	6.83	89.63	6.87	-1.719	0.086
MAP_6 hours	82.70	5.07	83.53	6.60	-0.834	0.404

The mean of Mean arterial pressure (mmHg) after shifting to PACU at all intervals of observations was comparable between both groups and was statistically non- significant. (Table 21, Figure 21)

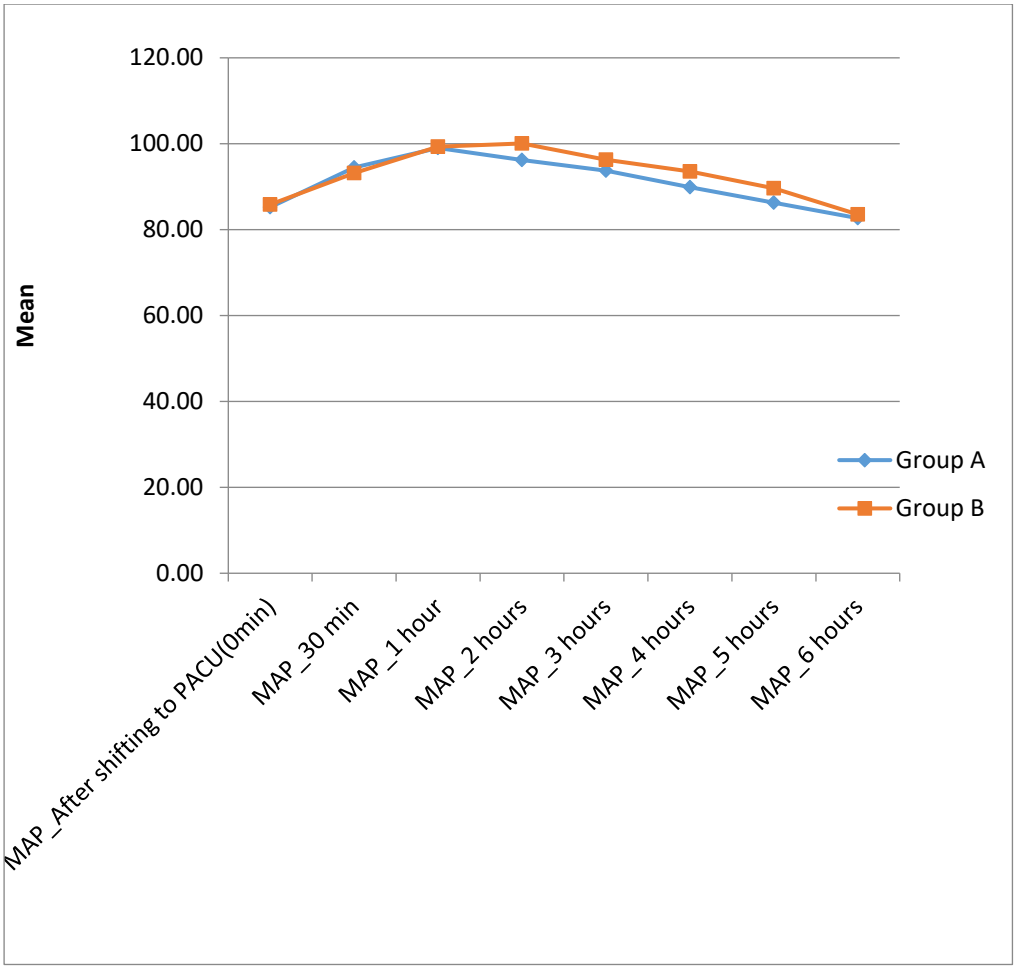

Figure 21: Mean Arterial Pressure (mmHg)

Table 22: Respiratory Rate (/min)

	Group A		Group B		Z	p-value
	Mean	SD	Mean	SD		
RR After shifting to PACU(0min)	16.20	1.10	16.07	0.98	-0.515	0.606
RR_30 min	18.10	1.58	17.93	0.94	-0.706	0.480
RR_1 hour	18.80	1.45	18.97	1.40	-0.439	0.660
RR_2 hours	18.17	1.49	18.83	1.72	-1.472	0.141
RR_3 hours	17.17	1.78	17.90	1.69	-1.854	0.064
RR_4 hours	16.43	1.59	17.00	1.66	-1.178	0.239
RR_5 hours	16.40	1.04	16.03	1.07	-1.482	0.138
RR_6 hours	15.43	0.97	15.23	1.22	-0.953	0.341

The mean respiratory rate (/min) after shifting to PACU at all intervals of observations was comparable between both groups and was statistically non- significant. (Table 22, Figure 22)

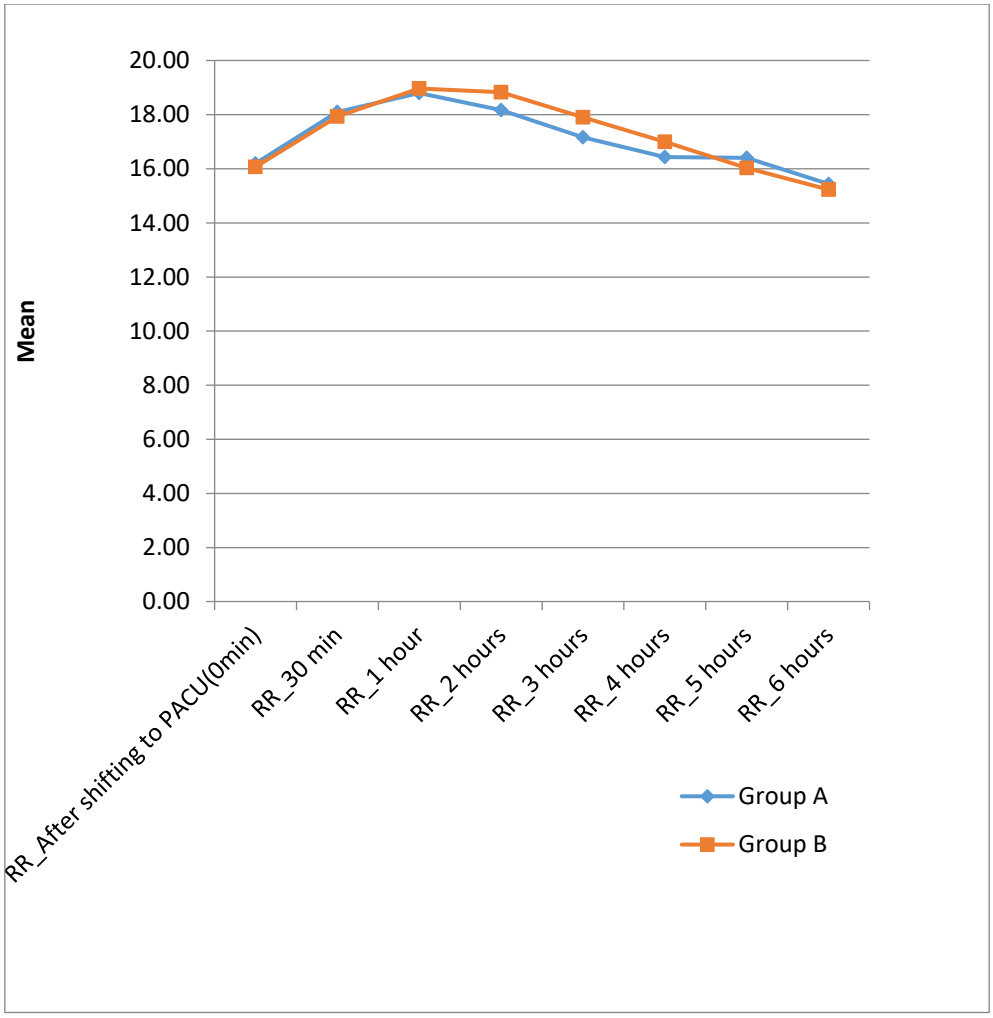

Figure 22: Respiratory Rate (/min)

Table 23: Oxygen saturation (Spo2)

	Group A		Group B		Z	p-value
	Mean	SD	Mean	SD		
SPO2 After shifting to PACU(0min)	97.10	0.55	97.03	0.41	-0.340	0.734
SPO2_30 min	97.93	0.37	97.77	0.50	-1.336	0.182
SPO2_1 hour	97.70	0.84	97.83	0.87	-0.728	0.467
SPO2_2 hours	97.43	1.01	97.47	1.01	0.000	1.000
SPO2_3 hours	97.67	0.88	97.40	1.07	-0.718	0.473
SPO2_4 hours	97.73	0.98	97.60	1.10	-0.401	0.688
SPO2_5 hours	97.70	0.99	97.53	1.07	-0.694	0.487
SPO2_6 hours	97.93	0.83	98.03	1.22	-1.154	0.249

The mean Oxygen saturation (Spo2) after shifting to PACU at all intervals of observations was comparable between both groups and was statistically non- significant. (Table 23, Figure 23)

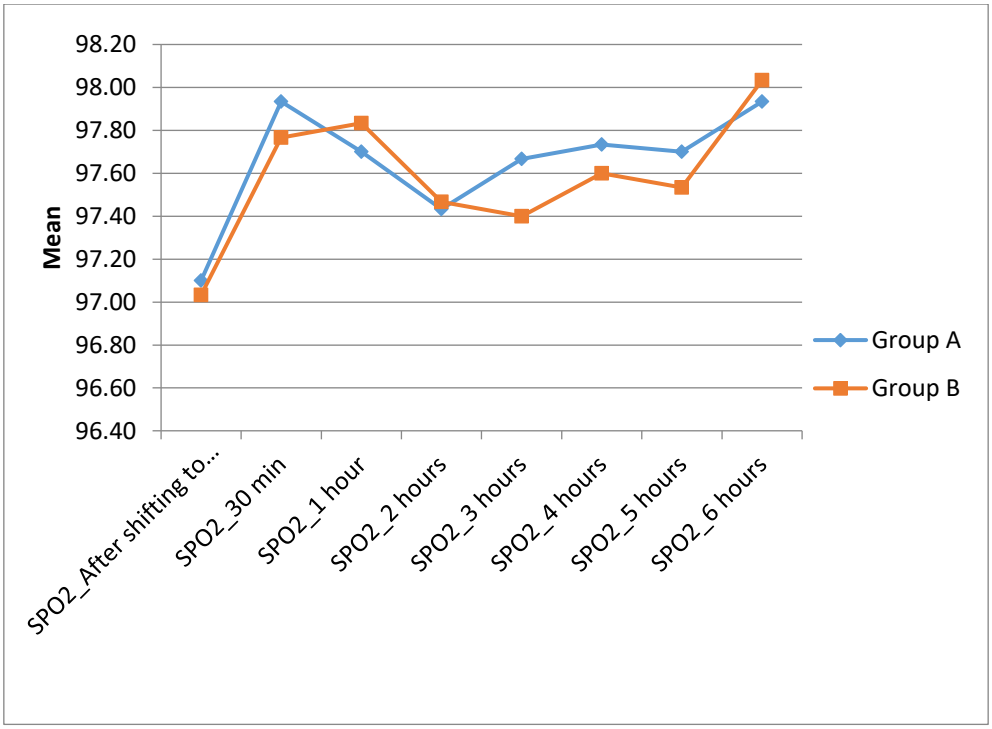

Figure 23: Oxygen saturation (Spo2)

Table 24: Adverse effects

		Group A		Group B		Total	Chi-square value	p-value
		No. of cases	%age	No. of cases	%age			
ADVERSE EFFECT	Blurred Vision	0	0.0%	2	6.7%	2	13.333	0.020
	Dizziness	2	6.7%	0	0.0%	2		
	Dry Mouth	0	0.0%	2	6.7%	2		
	Hypertension	0	0.0%	2	6.7%	2		
	Tachycardia	0	0.0%	4	13.3%	4		
	Nil	28	93.3%	20	66.7%	48		
RECOVERED OR NOT WITHIN 6 HOURS	Recovered	2	100.0%	10	100.0%	12		

Two patients (6.7%) in group A complained of dizziness while in group B; 2 patients complained of blurred vision, while the incidence of dry mouth and hypertension was 6.7% and that of tachycardia was 13.3% in group B as compared to 0% in Group A. Overall the incidence of adverse effects in group A was less (6.7%) as compared to Group B (33.3%) and this difference was statistically significant with p value of 0.020. Moreover all the adverse effects in both groups recovered within 6 hours (Table 24, Figure.24)

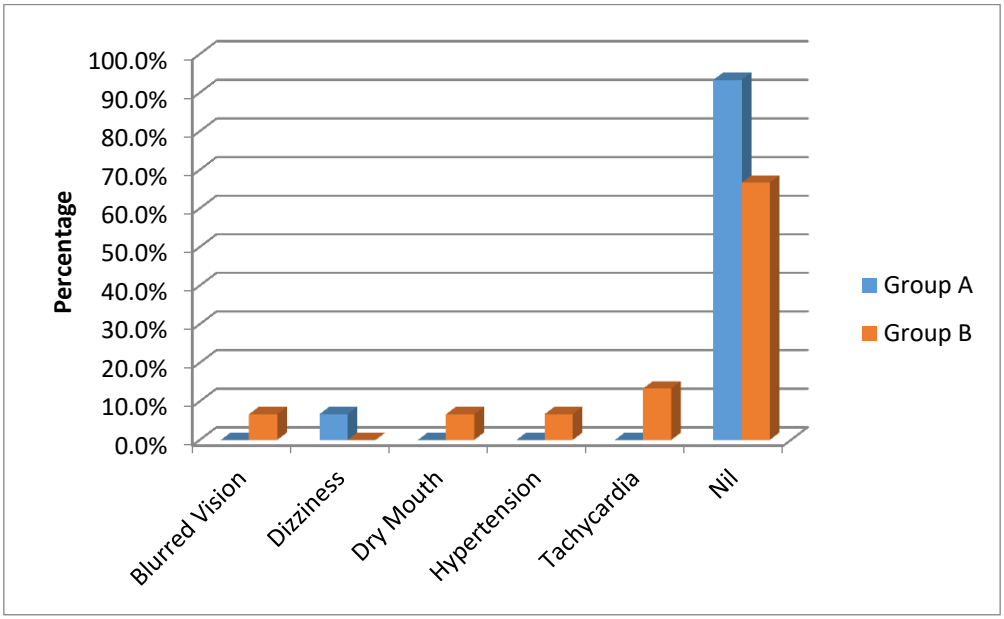

Figure 24: Adverse effects

DISCUSSION

CRBD in post-operative period is a common problem encountered by patients who have had urinary catheterization during various surgical procedures. It is distressing for the patient and challenging condition to manage for medical professionals in the PACU. It is a fairly common entity with incidence ranging between 47-90% and 38-57% patients report CRBD of moderate to severe grade. [1, 3]

The symptoms of CRBD are similar to OAB. They include pain and discomfort in the suprapubic region, burning sensation, urinary frequency and urgency with or without urge incontinence. The symptoms can worsen with increasing severity of CRBD and may be associated with behavioural responses such as a strong vocal response, flailing extremities and an attempt to pull out the urinary catheter.

Although various treatment modalities have been described in the literature yet CRBD is poorly understood and untreated by health care professionals. Untreated CRBD results in EA, delays patient discharge from hospital and increases the cost effectiveness of hospital stay.

In our study after the patients were shifted to PACU, they were closely observed for CRBD and its severity initially for 30 min for 1 hour and thereafter 1 hourly up to 6 hours post operatively. The severity of CRBD was assessed using CRBD scoring grade and NRS for CRBD.The patients who complained of Grade 2 and 3 CRBD were randomly divided into two study groups. Patients were also assessed for sedation and need for supplemental analgesia. None of the patients were excluded and all the enrolled patients completed the study.

CRBD is thought to be mediated via M3 subtype of muscarinic receptors, therefore anticholinergic agents like hyoscine have a well-established role in the prevention and management of CRBD .[59]The onset of IV hyoscine is about 9 minutes with peak action at 20-60 minutes and elimination half-life ranging from 1-5hours. [17]Hyoscine does not cross BBB due to presence of butyl-bromide and therefore it is devoid of central nervous system effects.

Antihistaminic in addition also have an analgesic and sedative properties. These drugs are competitive inhibitors of muscarinic receptors and thus can be used in management and prevention of CRBD. CPM is a first generation antihistamine. In et al studied CPM in relation to prevention of CRBD and found it be effective in decreasing the incidence of moderate CRBD when compared with placebo. [57]

Similarly YU-Yu Li et al studied prophylactic diphenhydramine for prevention of CRBD in gynaecological surgeries and found it be effective when compared with placebo group [18] Pheniramine is another antihistamine that belongs to moderately sedative class of first generation antihistamines. It is used in a dose of 0.3mg/kg for treatment of allergic conditions and is readily available in PACU.[60] Pheniramine has not been studied at all in relation to CRBD and it may prove beneficial in managing CRBD.The present study, therefore, was planned to study the comparative efficacy of pheniramine and hyoscine for management of post-operative CRBD.

The patients in both the groups were comparable with respect to age, height, weight, BMI and ASA physical status and mean time of administration of drug for CRBD. This is important as uniformity of demographic profile in both groups ensured that there are no confounding factors in the study.

Patients who were allocated to Group A were administered IV 22.75 mg pheniramine after diluting it with normal saline to make a total volume of 10 ml.

Patients who were enrolled in group B were administered IV hyoscine in a dose of 20 mg since this dose corresponds to clinically efficacious dose reported in the literature. Ryu et al used hyoscine for treatment of CRBD and compared it with placebo and found that 20 mg of hyoscine is effective in decreasing the severity of CRBD and need for rescue analgesic without adverse effects. [53] Similarly Salama et al compared hyoscine with ketamine and found hyoscine (20mg) to be more effective than ketamine in first 30 min for management of CRBD. [26] Nam et al administered 20 mg IV hyoscine for prevention of CRBD

just prior to end of extubation and compared it with the control group and found hyoscine to be beneficial in reducing incidence of CRBD. [61] Similarly Sabetian et al used 20 mg IV hyoscine for prevention of CRBD and demonstrated it to be efficacious in preventing CRBD.[62]

SEVERITY OF CRBD

It was observed that in both groups; symptoms of CRBD subsided after administration of study drug; however the resolution of CRBD symptoms was better in Group A than in Group B and was statistically significant at 2 hr, 3hr, 4hr, and 5hr. This suggests that IV pheniramine is more efficacious than IV hyoscine in managing post-operative CRBD.It is also noteworthy that this difference became insignificant at 6 hours post-operatively.

Our findings on pheniramine are similar to that observed by In et al. They studied effect of CPM on preventing CRBD and compared it with control group and found it be more effective in preventing the moderate grade CRBD.[57]

Salama et al studied ketamine and hyoscine for management of post-operative CRBD .They observed visual analog scale score for CRBD post-operatively for 4 hours. They reported that IV hyoscine is more efficacious in managing CRBD than IV ketamine. [26]

In the another study Ryu et al compared IV hyoscine with control group for treatment of CRBD and found it to be effective in managing CRBD post-operatively.[53]

On the contrary, Sabetian et al found that IV hyoscine was only statistically significant in prevention of post-operative CRBD than normal saline up to 30 minutes after injection. They used rescue medication (meperdine) in control group which itself has good pharmacological efficacy in treatment of CRBD and this might have confounded their interpretations. However it is important to note that the total utilized meperdine doses and time to discharge were significantly lower in intervention group than those of control group, suggesting that hyoscine contributed in the management of CRBD in the study by Sabetian et al.[62]

TIME TAKEN FOR RESOLUTION OF CRBD (MIN)

We observed that the time taken for resolution of CRBD was significantly less in Group A (80min ±43.39) as compared to Group B (145min ± 76.01) and this difference was statistically significant (p value 0.001). It is pertinent to mention here that our observation intervals were spaced at 1 hour. Despite the thorough search of literature, we could not find any study where time for resolution of CRBD symptoms were noted for either hyoscine or pheniramine.

RESCUE DRUG FOR CRBD ADMINISTRATION

In our study we observed that dose of rescue drug for CRBD i.e. tramadol was significantly less in Group A (5mg±15.26) as compared to Group B (48.33 mg±40.44)(p value 0.001).It was also observed that patients in Group B required tramadol administration much earlier than in Group A and this difference was statistically significant. In addition, the need for multiples dosages of tramadol as rescue drug were much higher in Group B than in Group A. All the above findings strongly support the efficacy of pheniramine for management of CRBD.

In et al also concluded that need for tramadol administration (rescue drug) was less in CPM group than in control group. Moreover the need for multiple dosages of tramadol were significant with more requirement in control group.[57] However this study suffered from one drawback that they did not standardize the size of foley's catheter as size of catheter is an independent risk factor for CRBD. So to eliminate this confounding factor we chose uniform size of foley's catheter for all patients.

The efficacy of hyoscine for management of CRBD has been explained by Sabetian et al. They used meperidine as rescue drug to treat patients with severe CRBD and observed that the total meperidine dose required was significantly lower in hyoscine group than in control group. [62]

NRS FOR PAIN AT SURGICAL SITE

It was observed that NRS for pain at surgical site was significantly less in Group A than in Group B at 1hour, 2hour, 3 hour and 4 hours. It was

also recorded that this difference became insignificant at 5 hours and 6 hours post-operatively. This suggests that IV pheniramine could have contributed to incision site pain relief as well.

This finding of our study is in concordance with study conducted by Shrestha et al who in 2014 studied effect of dexamethasone and pheniramine vs placebo in patients undergoing elective laparoscopic cholecystectomy and found that patients in intervention group experienced significant less surgical site pain during the 24 hour observation time than patients in placebo. [63]

RESCUE DRUG FOR SURGICAL SITE PAIN ADMINISTRATION

In our study we observed that dose of rescue drug for pain at surgical site i.e. fentanyl was significantly less in Group A (8.33mcg$\pm$18.95) as compared to Group B (35mcg$\pm$32.56) with p value being 0.001. We also observed that patients in Group B required administration of fentanyl earlier than in Group A.

The sedative and analgesic effect of IV pheniramine could have contributed to relief of pain at surgical site. [63]

It is also relevant to mention here that even hyoscine has been reported to reduce post-operative analgesic consumption. [53] We did not intend to study this effect, hence we did not compare hyoscine against placebo.

SEDATION SCORE

In our study we used Modified observers assessment of alertness sedation scale-(MOSS A) as a tool for measurement of alertness. We observed that Sedation score was significantly higher in Group B as compared to Group A with p value being 0.001 and 0.008 at 2 hours and 3 hours respectively. On next observation intervals this score became statistically insignificant .This can be attributed to central sedative effects of pheniramine which are absent in hyoscine.

Mansfield et al in 2003 conducted study on effects of fexofenadine, diphenhydramine, and placebo on performance of the test of variables of attention and concluded that diphenhydramine 50 mg caused

significant decrease in response time and increased self-reported drowsiness as compared with placebo.[64]

Salama et al used MOSS- A score to compare ketamine and hyoscine and concluded that the level of sedation was higher in ketamine group as compared to hyoscine group (p <0.001).[26]

Ryu et al used MOSS-A score to compare hyoscine with control group and observed that sedation scores were comparable between both groups pointing towards lack of sedative effects of hyoscine. [53]

This is in accordance with the clinical profile of hyoscine. Hyoscine being a quaternary compound and its attachment to butyl bromide; .doesn't cross BBB and hence doesn't cause sedation.

HAEMODYANMIC PARAMETERS

It was observed that SBP was significantly higher in Group B than in Group A at 2 hours, 4 hours and 5 hours. It is relevant to mention here that CRBD started at similar time interval. The increase in SBP might be attributed to either pain at surgical site or CRBD. Again; the increase in SBP subsided after 4-5hours once CRBD subsided.

Salama et al observed that among patients who received either ketamine or hyoscine there was no significant difference in MAP.[26]

Similarly Ryu et al found a significant increase in HR in butylscopolamine group as compared to control (p=0.02) while the difference in MAP was not significant. [53]

ADVERESE EFFECTS

In our study we observed that Group A patients had reduced incidence of adverse effects as compared to Group B and was statistically significant with p value of 0.021. In Group A 2, out of 30 patients (6.7%) experienced 1 episode of dizziness. This adverse effect can be attributed to antihistaminic nature of pheniramine.

In Group B, 10 out of 30 patients (33.33) experienced adverse effects. Out of which 2 patients had 1 episode of blurred vision, dry mouth, and hypertension. 4 patients (13.3%) had 1 episode of tachycardia. These

adverse effects in patients receiving hyoscine may be due to anticholinergic nature of hyoscine.

These adverse effects in both groups were not worrisome as all adverse effects subsided within 6 hours of observation of their own.

Our findings were consistent with the study of Ryu et al who also found that patients receiving hyosicne had tachycardia, dry mouth during their stipulated time intervals. [53]

Similarly Salama et al found that increase in HR was significantly higher in hyoscine group than ketamine group. [26] Sabetian et al also found that 8 out of 24 patients had dry mouth who were given hyoscine as intervention drug. [62] All these adverse effects of hyoscine may be attributed to their anticholinergic action.

Thus we observed that IV pheniramine is more effective than IV hyoscine in managing CRBD in non- urological studies. It helped to resolve CRBD earlier than IV hyoscine with less need of rescue drug for CRBD and surgical site pain. But it was associated with less MOSS-A sedation score than IV hyoscine. Also patients experienced less adverse effects than IV hyoscine.

Certain limitations of our study are worth mentioning.

1. We enrolled only non –urological and non-gynaecological surgeries because these surgeries predispose patients to CRBD. Evaluating pheniramine for urological and gynaecological surgeries would be interesting since that would establish its role for management of CRBD.
2. The observations intervals for CRBD were kept at 1 hour in our study considering the time of onset of hyoscine. More frequent intervals of observation may yield more data which can help eliminate the time of resolution of symptom of CRBD after administration of pheniramine and hyoscine.
3. The study was conducted using single dose of pheiramine. Dose-response studies can be planned in future to find an effective dose with minimal adverse effects.

SUMMARY & CONCLUSION

The present study was conducted in the Department of Anaesthesia, Dayanand Medical College and Hospital, Ludhiana after approval from Institutional Ethics Committee. 60 ASA I and II patients, between 25-55 years of age, posted for elective non-urological surgeries who complained of grade 2 and 3 CRBD were enrolled for this prospective, double blind, randomized controlled trial. Patients were randomly allotted to two groups of 30 patients each.

The technique of general anaesthesia was standardized in both groups.

Group A patients were administered Injection Pheniramine 22.75 mg IV.

Group B patients were administered Injection Hyoscine 20 mg IV.

Both drugs were diluted with normal saline to make a total volume of 10 ml in identical syringes. Follow up of patients was done by an anaesthesia resident blinded to the study drugs administered. At each observation interval, post-operative pain as assessed by NRS, HR, MAP, NRS score for CRBD and sedation score of patient was also recorded. The follow up assessment was performed at 30 min, 1 hours and every subsequent hour for 6 hours. During each evaluation, the patient was also asked to determine whether the pain was related to CRBD or to the wound of surgery. Any patient complaining of pain, or reporting NRS ≥4 for pain at surgical site or demanding an analgesic was administered fentanyl 50 mcg IV. The time of administration of rescue analgesic and NRS at that time were recorded. Patients still complaining of CRBD grade 2 or 3 at subsequent observation intervals were managed with rescue dose of tramadol 50 mg, which was recorded.

Sedation was evaluated using a Modified Observer's Assessment of Alertness/Sedation score (given below) at the each observation time interval.

All patients were continuously monitored and any episode of bradycardia (defined as Heart rate < 60/ min) or tachycardia (defined as Heart rate > 100/ min) were noted.

Any episode of hypotension defined as (MAP below 20 % of pre-anaesthetic levels) or hypertension (MAP above 20 % of pre-anaesthetic levels) was also recorded.

The following conclusions were drawn during the study period:

- Both the groups were comparable with respect to demographic data, ASA physical status as well as mean time of administration of drug for CRBD.
- The severity of CRBD was significantly reduced in Group A (1.13±0.82, 0.50±0.94, 0.27±0.64 and 0.10±0.31 at 2, 3, 4 and 5 hours respectively) as compared to Group B (1.80±0.61, 1.40±0.72, 1.00±0.79 and 0.53±0.57 at same observation intervals) (p value 0.001).
- Mean time taken for resolution of CRBD was significantly less in Group A (80 ±43.39min) as compared to Group B (145 ± 76.01min) (p value 0.001)
- Mean rescue dose of tramadol was significantly reduced in Group A (5mg±15.26) as compared to Group B (48.33 mg±40.44) (p value 0.001).
- Mean time of tramadol administration was significantly reduced in Group A than in Group B.
- For individual patients, tramadol requirement was less frequent (none in 27 patients, once in 3 patients) in Group A as compared to Group B (none in 10 patients, once in 11 patients and twice in 9 patients).
- Mean NRS for surgical site pain was significantly reduced in Group A than in Group B at 1, 2, 3 and 4 hours.
- Mean requirement of fentanyl for post-operative pain was significantly decreased in Group A than in Group B.
- Mean time of fentanyl administration was significantly earlier in Group A than in Group B.

- Mean MOSS- A sedation score was significantly reduced in Group A than in Group B at 2 and 3 hours.
- Both the groups were comparable with respect to urine output, HR, DBP, MAP, RR, and SPO2.
- Mean SBP was significantly lower in Group A than in Group B at 2 hour, 4 hours and 5 hours.
- Group A experienced significantly reduced incidence of adverse effects than in Group B (p value 0.021) and all adverse effects recovered within 6 hours.

  Hence, we conclude that IV Pheniramine is more effective than IV Hyosicne in managing post- operative CRBD. It also decreased requirement of analgesic for post-operative pain. Moreover pheniramine had lesser adverse effects but was associated with lesser MOSS- A sedation score than IV hyoscine.

  The above findings suggest that IV Pheniramine can be effectively used to treat post-operative CRBD with reduced requirement of rescue drug and lesser adverse effects.

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S. No.	MRD NO.	Name	Age(Years)	Diagnosis	Surgery Performed	Height(Feet)	Weight(kg)	BMI	ASA	Anaesthesia Start : Date/Time
1	935117	JS	45	Frontal space occuping lesion	Frontal space occuping lesion excision	5feet 8 inches	80	26.8	2	19-03-2021 09:30am
2	1114286	SS	30	Right Frontal Space occuping lesion	Right Frontal Space occuping lesion excision	5 feet 10 inches	85	26.9	2	03-06-2021 09:00am
3	984897	MS	26	P/0/C/0 Decompressive craniectomy	Cranioplasty	5 feet 10 inches	85	26.9	1	22-06-2021 11:00am
4	1010354	PK	26	P/0/C/0 Decompressive craniectomy	Cranioplasty	5 feet 10 inches	80	25.3	2	23-06-2021 10:00am
5	1143923	HS	39	L3 fracture	L3 fixation	5 feet 7 inches	82	28.3	1	29-07-2021 10:00am
6	1043530	RS	32	P/0/C/0 Decompressive craniectomy	Cranioplasty	5 feet 8 inches	70	23.5	1	04-08-2021 12:00pm
7	1152801	SK	38	Sub dural haemotoma	Burr Hole	5 feet 6 inches	72	25.6	2	12-08-2021 11:00am
8	1128324	G	50	Cholelithiasis	laproscopic cholecystectomy	5 feet 9 inches	82	26.7	2	16-08-2021 10:00am
9	1144198	HM	29	Dorsal spine fracture	Dorsal spine Fixation	5 feet 10 inches	89	28.2	1	17-08-2021 09:00am
10	1146709	RS	42	Prolapsed Intervertebral Disc	Microdissectomy	5 feet 7 inches	60	20.7	1	18-08-2021 09:00am
11	1162670	SS	36	Intestinal Obstruction	Exploratory Laprotomy	5 feet 10 inches	90	28.5	2	01-09-2021 11:00am
12	743693	RK	53	Umblical Hernia	ETEP	5 feet 8 inches	82	27.5	2	01-09-2021 11:00am
13	1186766	KK	49	Open globe injury	Globe Repair	5 feet 11 inches	92	28.3	2	07-10-2021 2:00pm
14	1210051	RS	45	Cauda Equina Syndrome	Laminectomy & Dissectomy	5 feet 8 inches	80	26.8	2	20-11-2021 09:00am
15	1212547	VK	30	D11 fracture	D11 Fixation	5 feet 10 inches	86	27.2	2	27-11-2021 10:00am
16	1213674	RS	31	L1 fracture	L1 fracture fixation	5 feet 8 inches	80	26.8	1	07-12-2021 09:00am
17	1164802	N	25	P/0/C/0 Decompressive craniectomy	Cranioplasty	5 feet 10 inches	80	25.3	1	07-12-2021 10:00am
18	1160005	SS	33	P/0/C/0 Decompressive craniectomy	Cranioplasty	5 feet 6 inches	76	27	2	22-12-2021 10:00am
19	1225185	RL	45	Sub dural haemotoma	Burr Hole	5 feet 4 inches	60	22.7	2	30-12-2021 11:00am
20	1232827	RS	52	Fracture Proximal Humerus	PHILOS	5 feet 10 inches	90	28.5	1	07-01-2022 12:00pm
21	1234161	S	46	D12 IDEM	Excision	5 feet 8 inches	86	28.8	1	07-01-2022 9:00am
22	1175412	JS	34	P/0/C/0 Decompressive craniectomy	Cranioplasty	5 feet 10 inches	85	26.9	1	08-01-2022 10:00am
23	1235432	S	55	Space occuping lesion	Space occuping lesion excision	5 feet 6 inches	72	25.6	1	12-01-2022 9:00am
24	1244401	K	36	L4 L5 PIVD	Laminectomy & Dissectomy	5 feet 10 inches	90	28.5	2	26-01-2022 10:00am
25	1248480	GS	35	L5 S1 PIVD	Laminectomy & Dissectomy	5 feet 11 inches	92	28.3	2	05-02-2022 11:00am
26	4286	WS	55	L3 L4 PIVD	Laminectomy & Dissectomy	5 feet 11 inches	80	24.6	2	08-02-2022 9:00am
27	1128371	GS	42	P/0/C/0 Decompressive craniectomy	Cranioplasty	6 feet	100	29.9	1	02-03-2022 12:30pm
28	1188062	HS	32	P/0/C/0 Decompressive craniectomy	Cranioplasty	5 feet 6 inches	76	27	1	04-03-2022 10:00am
29	1268314	G	53	Left Temporo-Parietal Glioma	Excision	5 feet 8 inches	80	26.8	2	15-03-2022 9:00am
30	1268919	HR	55	Sub dural haemotoma	Burr Hole	5 feet 6 inches	75	26.7	2	15-03-2022 12:00pm
31	1245051	BK	54	Intestinal Obstruction	Exxploratory Laprotomy	5 feet 6 inches	70	24.9	2	17-03-2022 10:00am
32	1270911	IS	27	Deviated Nasal Septum	Septoturbinoplasty	6 feet	90	26.9	1	17-03-2022 8:30am
33	1276386	S	47	Appendicitis	Laproscopic Appendectomy	5 feet 6 inches	76	27	1	28-03-2022 9:00am
34	1277168	J	53	Cholelithiasis	Laproscopic Cholecystectomy	5 feet 6 inches	70	24.9	1	28-03-2022 10:00am
35	1277011	KS	38	Sub acute Intestinal Obstruction	Exploratory Laprotomy	5 feet 10 inches	80	25.3	2	28-03-2022 11:00am
36	1248200	DS	25	Varicocele	Bilateral Varicocelectomy	5 feet 8 inches	80	26.8	1	28-03-2022 2:00pm
37	941549	D	55	P/0/C/0 Decompressive craniectomy	Cranioplasty	5 feet 6 inches	70	24.9	2	28-03-2022 2:00pm
38	1148438	RS	29	P/0/C/0 Decompressive craniectomy	Cranioplasty	5 feet 8 inches	80	26.8	1	29-03-2022 10:00am
39	1230235	RKG	45	P/0/C/0 Decompressive craniectomy	Cranioplasty	5 feet 10 inches	70	22.1	2	30-03-2022 9:00am

S. No.	MRD NO.	Name	Urinary Catheter insertion Date/Time	Surgery Start:Date/Time	Surgery Finish : Date/Time	Anaesthesia finish: Date/Time	Date/Time of Shifting to PACU	Grade of CRBD							
								After shifting to PACU(0min)	30 min	1 hour	2 hours	3 hours	4 hours	5 hours	6 hours
1	935117	JS	19-03-2021 09:40am	19-03-2021 09:45am	19-03-2021 02:00pm	19-03-2021 02:05pm	19-03-2021 02:10pm	0	1	3	2	2	1	0	0
2	1114286	SS	03-06-2021 09:10am	03-06-2021 09:20am	03-06-2021 01:00pm	03-06-2021 01:10pm	03-06-2021 01:20pm	0	2	3	1	0	0	0	0
3	984897	MS	22-06-2021 11:10am	22-06-2021 11:20am	22-06-2021 1:00pm	22-06-2021 1:10pm	22-06-2021 1:20pm	0	1	2	2	1	1	1	1
4	1010354	PK	23-06-2021 10:10am	23-06-2021 10:20am	23-06-2021 12:00pm	23-06-2021 12:10pm	23-06-2021 12:15pm	0	0	1	3	2	2	1	0
5	1143923	HS	29-07-2021 10:05am	29-07-2021 10:10am	29-07-2021 1:00pm	29-07-2021 1:05pm	29-07-2021 1:10pm	1	2	2	1	0	0	0	0
6	1043530	RS	04-08-2021 12:10pm	04-08-2021 12:15pm	04-08-2021 2:30pm	04-08-2021 2:40pm	04-08-2021 2:45pm	0	2	2	2	1	1	0	0
7	1152801	SK	12-08-2021 11:05am	12-08-2021 11:10am	12-08-2021 1:00pm	12-08-2021 1:05pm	12-08-2021 1:10pm	0	3	2	1	0	0	0	0
8	1128324	G	16-08-2021 10:05am	16-08-2021 10:10am	16-08-2021 12:00pm	16-08-2021 12:05pm	16-08-2021 12:10pm	0	1	2	2	1	0	0	0
9	1144198	HM	17-08-2021 09:10am	17-08-2021 09:20am	17-08-2021 1:00pm	17-08-2021 01:10pm	17-08-2021 01:20pm	0	1	2	0	0	0	0	0
10	1146709	RS	18-08-2021 09:05am	18-08-2021 09:10am	18-08-2021 12:00pm	18-08-2021 12:05pm	18-08-2021 12:10pm	0	1	3	2	2	2	1	0
11	1162670	SS	01-09-2021 11:10am	01-09-2021 11:15am	01-09-2021 2:00pm	01-09-2021 2:10pm	01-09-2021 2:20pm	0	1	3	1	0	0	0	0
12	743693	RK	01-09-2021 11:05am	01-09-2021 11:10am	01-09-2021 01:30pm	01-09-2021 01:40pm	01-09-2021 01:45pm	0	3	2	2	1	0	0	0
13	1186766	KK	07-10-2021 2:10pm	07-10-2021 2:20pm	07-10-2021 5:00pm	07-10-2021 5:10pm	07-10-2021 5:15pm	0	1	1	2	0	0	0	0
14	1210051	RS	20-11-2021 09:10am	20-11-2021 09:15am	20-11-2021 1:00pm	20-11-2021 1:05pm	20-11-2021 1:10pm	0	0	1	2	1	1	1	0
15	1212547	VK	27-11-2021 10:10am	27-11-2021 10:15am	27-11-2021 12:00pm	27-11-2021 12:05pm	27-11-2021 12:10pm	0	1	3	1	0	0	0	0
16	1213674	RS	07-12-2021 09:10am	07-12-2021 09:15am	07-12-2021 12:30pm	07-12-2021 12:40pm	07-12-2021 1 : 00pm	0	1	2	3	2	2	1	0
17	1164802	N	07-12-2021 10:10am	07-12-2021 10:20am	07-12-2021 12:30pm	07-12-2021 12:40pm	07-12-2021 12: 50pm	0	1	3	2	1	0	0	0
18	1160005	SS	22-12-2021 10:10am	22-12-2021 10:20am	22-12-2021 12:30pm	22-12-2021 12:50pm	22-12-2021 1:10pm	0	3	1	0	0	0	0	0
19	1225185	RL	30-12-2021 11:05am	30-12-2021 11:10am	30-12-2021 12:30pm	30-12-2021 12:40pm	30-12-2021 1:00pm	0	0	2	1	1	1	1	0
20	1232827	RS	07-01-2022 12:05pm	07-01-2022 12:10pm	07-01-2022 2:00pm	07-01-2022 2:05pm	07-01-2022 2:10pm	0	1	1	3	1	0	0	0
21	1234161	S	07-01-2022 9:10am	07-01-2022 9:20am	07-01-2022 12:00pm	07-01-2022 12:10pm	07-01-2022 12:20pm	0	1	2	3	2	1	0	0
22	1175412	JS	08-01-2022 10:10am	08-01-2022 10:20am	08-01-2022 12:30pm	08-01-2022 12:45pm	08-01-2022 1:00pm	0	1	3	1	0	0	0	0
23	1235432	S	12-01-2022 9:10am	12-01-2022 9:20am	12-01-2022 2:00pm	12-01-2022 2:10pm	12-01-2022 2:20pm	0	1	3	1	0	0	0	0
24	1244401	K	26-01-2022 10:05am	26-01-2022 10:10am	26-01-2022 1:00pm	26-01-2022 1:10pm	26-01-2022 1:20pm	1	2	2	1	0	0	0	0
25	1248480	GS	05-02-2022 11:10am	05-02-2022 11:15am	05-02-2022 03:00pm	05-02-2022 03:10pm	05-02-2022 03:20pm	0	1	2	1	0	0	0	0
26	4286	WS	08-02-2022 9:10am	08-02-2022 9:15am	08-02-2022 12:15pm	08-02-2022 12:20pm	08-02-2022 12:30pm	0	1	2	2	2	2	1	0
27	1128371	GS	02-03-2022 12:35pm	02-03-2022 12:40pm	02-03-2022 3:00pm	02-03-2022 3:10pm	02-03-2022 3:15pm	0	1	3	2	2	2	1	0
28	1188062	HS	04-03-2022 10:05am	04-03-2022 10:10am	04-03-2022 12:00pm	04-03-2022 12:05pm	04-03-2022 12:10pm	0	2	0	0	0	0	0	0
29	1268314	G	15-03-2022 9:05am	15-03-2022 9:10am	15-03-2022 01:50pm	15-03-2022 01:55pm	15-03-2022 02:00pm	0	1	2	1	0	0	0	0
30	1268919	HR	15-03-2022 12:05pm	15-03-2022 12:10pm	15-03-2022 1:00pm	15-03-2022 1:05pm	15-03-2022 1:10pm	0	3	2	1	0	0	0	0
31	1245051	BK	17-03-2022 10:05am	17-03-2022 10:10am	17-03-2022 2:15pm	17-03-2022 2:20pm	17-03-2022 2:30pm	0	2	2	2	1	1	1	0
32	1270911	IS	17-03-2022 8:40am	17-03-2022 8:45am	17-03-2022 10:30am	17-03-2022 10:40am	17-03-2022 10:50am	0	0	0	1	3	2	1	0
33	1276386	S	28-03-2022 9:10am	28-03-2022 9:15am	28-03-2022 12:00pm	28-03-2022 12:05pm	28-03-2022 12:20pm	0	1	2	1	1	0	0	0
34	1277168	J	28-03-2022 10:05am	28-03-2022 10:10am	28-03-2022 1:00pm	28-03-2022 1:05pm	28-03-2022 1:10pm	0	2	2	1	1	0	0	0
35	1277011	KS	28-03-2022 11:05am	28-03-2022 11:10am	28-03-2022 2:30pm	28-03-2022 2:40pm	28-03-2022 2:50pm	0	0	0	1	3	2	1	0
36	1248200	DS	28-03-2022 2:10pm	28-03-2022 2:20pm	28-03-2022 4:00pm	28-03-2022 4:10pm	28-03-2022 4:20pm	0	1	3	2	1	1	0	0
37	941549	D	28-03-2022 2:10pm	28-03-2022 2:20pm	28-03-2022 4:30pm	28-03-2022 4:40pm	28-03-2022 4:50pm	0	0	2	3	3	2	2	0
38	1148438	RS	29-03-2022 10:05am	29-03-2022 10:10am	29-03-2022 12:00pm	29-03-2022 12:05pm	29-03-2022 12:10pm	0	1	3	2	2	1	0	0
39	1230235	RKG	30-03-2022 9:05am	30-03-2022 9:10am	30-03-2022 11:15am	30-03-2022 11:20am	30-03-2022 11:30am	0	1	3	2	2	2	1	0

S. No.	MRD NO.	Name	NRS for pain related to CRBD								Treatment administered				
			After shifting to PACU(0min)	30 min	1 hour	2 hours	3 hours	4 hours	5 hours	6 hours	After shifting to PACU(0min)	30 min	1 hour	2 hours	3 hours
1	935117	JS	0	2	6	4	4	3	1	0	-	-	Phenriamine 22.75Mg	-	-
2	1114286	SS	0	5	6	2	0	0	0	0	-	Phenriamine 22.75Mg	-	-	-
3	984897	MS	0	3	5	5	3	2	2	2	-	-	Hyoscine 20 Mg	-	-
4	1010354	PK	0	1	1	6	5	4	2	0	-	-	-	Phenriamine 22.75Mg	-
5	1143923	HS	2	5	4	1	0	0	0	0	-	Phenriamine 22.75Mg	-	-	-
6	1043530	RS	0	5	5	6	3	2	1	0	-	Hyoscine 20 Mg	-	-	-
7	1152801	SK	1	5	4	2	1	0	0	0	-	Phenriamine 22.75Mg	-	-	-
8	1128324	G	0	2	5	4	2	1	0	0	-	-	Phenriamine 22.75Mg	-	-
9	1144198	HM	0	2	4	0	0	0	0	0	-	-	Phenriamine 22.75Mg	-	-
10	1146709	RS	0	3	6	5	5	5	2	0	-	-	Hyoscine 20 Mg	-	-
11	1162670	SS	0	1	6	3	1	0	0	0	-	-	Phenriamine 22.75Mg	-	-
12	743693	RK	0	6	5	4	3	1	0	0	-	Hyoscine 20 Mg	-	-	-
13	1186766	KK	0	2	3	4	0	0	0	0	-	-	-	Phenriamine 22.75Mg	-
14	1210051	RS	0	1	2	4	3	2	2	0	-	-	-	Hyoscine 20Mg	-
15	1212547	VK	0	2	6	2	1	0	0	0	-	-	Phenriamine 22.75Mg	-	-
16	1213674	RS	0	2	4	8	6	4	2	0	-	-	Hyoscine 20 Mg	-	-
17	1164802	N	1	3	7	4	2	0	0	0	-	-	Phenriamine 22.75Mg	-	-
18	1160005	SS	0	6	3	1	0	0	0	0	-	Phenriamine 22.75Mg	-	-	-
19	1225185	RL	0	1	4	3	2	1	1	0	-	-	Hyoscine 20 Mg	-	-
20	1232827	RS	0	1	2	6	2	1	0	0	-	-	-	Phenriamine 22.75Mg	-
21	1234161	S	0	1	4	6	4	3	1	0	-	-	Hyoscine 20 Mg	-	-
22	1175412	JS	0	2	6	3	1	0	0	0	-	-	Phenriamine 22.75Mg	-	-
23	1235432	S	0	2	7	3	1	0	0	0	-	-	Phenriamine 22.75Mg	-	-
24	1244401	K	2	4	4	2	1	0	0	0	-	Hyoscine 20 Mg	-	-	-
25	1248480	GS	0	2	4	3	1	0	0	0	-	-	Hyoscine 20 Mg	-	-
26	4286	WS	1	2	4	4	5	4	3	0	-	-	Hyoscine 20 Mg	-	-
27	1128371	GS	0	2	7	5	4	3	1	0	-	-	Hyoscine 20 Mg	-	-
28	1188062	HS	0	5	1	0	0	0	0	0	-	Phenriamine 22.75Mg	-	-	-
29	1268314	G	0	2	4	2	1	0	0	0	-	-	Phenriamine 22.75Mg	-	-
30	1268919	HR	0	8	4	2	1	0	0	0	-	Phenriamine 22.75Mg	-	-	-
31	1245051	BK	0	6	5	4	3	2	1	0	-	Hyoscine 20 Mg	-	-	-
32	1270911	IS	0	0	0	2	7	4	2	0	-	-	-	-	Phenriamine 22.75Mg
33	1276386	S	0	2	4	2	1	0	0	0	-	-	Hyoscine 20Mg	-	-
34	1277168	J	0	5	4	4	3	2	1	0	-	Hyoscine 20Mg	-	-	-
35	1277011	KS	0	0	0	2	7	4	2	0	-	-	-	-	Pheniramine 22.75Mg
36	1248200	DS	0	2	6	4	4	3	1	0	-	-	Hyoscine 20Mg	-	-
37	941549	D	0	0	1	5	7	4	3	0	-	-	Hyoscine 20Mg	-	-
38	1148438	RS	0	2	5	4	4	3	1	0	-	-	Pheniramine 22.75Mg	-	-
39	1230235	RKG	0	2	7	6	4	2	1	0	-	-	Hyoscine 20Mg	-	-

S. No.	MRD NO.	Name				Time taken for resolution of CRBD(min)	Rescue dose of Tramadol for CRBD								Frequency of Tramadol administration	NRS for pain at surgical site					
			4 hours	5 hours	6 hours		After shifting to PACU(0min)	30 min	1 hour	2hours	3 hours	4 hours	5 hours	6 hours		After shifting to PACU (0min)	30 min	1 hour	2 hours	3 hours	4 hours
1	935117	JS	-	-	-	180	-	-	-	-	-	-	-	-	-	1	2	2	1	2	1
2	1114286	SS	-	-	-	60	-	-	-	-	-	-	-	-	-	2	4	4	5	3	2
3	984897	MS	-	-	-	120	-	-	-	50 Mg	-	-	-	-	1	2	3	3	3	5	3
4	1010354	PK	-	-	-	180	-	-	-	-	-	50Mg	-	-	1	0	0	0	2	0	0
5	1143923	HS	-	-	-	90	-	-	-	-	-	-	-	-	-	0	3	6	4	3	2
6	1043530	RS	-	-	-	150	-	-	50 Mg	50Mg	-	-	-	-	2	2	3	5	6	6	3
7	1152801	SK	-	-	-	90	-	-	-	-	-	-	-	-	-	0	2	1	0	0	0
8	1128324	G	-	-	-	120	-	-	-	-	-	-	-	-	-	0	1	0	0	0	0
9	1144198	HM	-	-	-	60	-	-	-	-	-	-	-	-	-	0	0	0	0	0	0
10	1146709	RS	-	-	-	240	-	-	-	50Mg	-	50Mg	-	-	2	1	2	5	4	5	3
11	1162670	SS	-	-	-	60	-	-	-	-	-	-	-	-	-	0	0	0	0	1	0
12	743693	RK	-	-	-	150	-	-	-	50Mg	-	-	-	-	1	0	0	1	0	0	0
13	1186766	KK	-	-	-	60	-	-	-	-	-	-	-	-	-	0	0	0	0	0	0
14	1210051	RS	-	-	-	60	-	-	-	-	-	-	-	-	-	0	1	2	6	4	2
15	1212547	VK	-	-	-	60	-	-	-	-	-	-	-	-	-	0	0	0	0	0	0
16	1213674	RS	-	-	-	240	-	-	-	50Mg	-	50Mg	-	-	2	0	2	6	5	6	2
17	1164802	N	-	-	-	120	-	-	-	-	-	-	-	-	-	0	1	0	0	0	0
18	1160005	SS	-	-	-	30	-	-	-	-	-	-	-	-	-	0	0	0	0	0	0
19	1225185	RL	-	-	-	60	-	-	-	-	-	-	-	-	-	0	2	4	6	3	2
20	1232827	RS	-	-	-	60	-	-	-	-	-	-	-	-	-	0	1	2	4	5	2
21	1234161	S	-	-	-	120	-	-	-	50Mg	-	-	-	-	1	0	0	1	0	2	0
22	1175412	JS	-	-	-	60	-	-	-	-	-	-	-	-	-	0	0	0	0	0	0
23	1235432	S	-	-	-	60	-	-	-	-	-	-	-	-	-	0	0	0	0	0	0
24	1244401	K	-	-	-	90	-	-	-	-	-	-	-	-	-	0	0	0	0	0	0
25	1248480	GS	-	-	-	60	-	-	-	-	-	-	-	-	-	0	0	0	1	0	0
26	4286	WS	-	-	-	240	-	-	-	-	50Mg	-	50Mg	-	2	0	2	6	4	5	4
27	1128371	GS	-	-	-	240	-	-	-	-	50Mg	50Mg	-	-	2	0	2	4	4	2	1
28	1188062	HS	-	-	-	30	-	-	-	-	-	-	-	-	-	0	0	0	0	0	0
29	1268314	G	-	-	-	60	-	-	-	-	-	-	-	-	-	0	2	3	4	2	1
30	1268919	HR	-	-	-	90	-	-	-	-	-	-	-	-	-	0	0	0	0	0	0
31	1245051	BK	-	-	-	150	-	-	-	-	50Mg	-	-	-	1	0	0	4	3	2	1
32	1270911	IS	-	-	-	120	-	-	-	-	-	50Mg	-	-	1	0	0	0	0	0	0
33	1276386	S	-	-	-	60	-	-	-	-	-	-	-	-	-	0	0	0	0	0	0
34	1277168	J	-	-	-	90	-	-	-	-	-	-	-	-	-	0	0	4	4	3	2
35	1277011	KS	-	-	-	120	-	-	-	-	-	50Mg	-	-	1	0	0	0	0	0	0
36	1248200	DS	-	-	-	120	-	-	-	50Mg	-	-	-	-	1	0	0	0	2	6	4
37	941549	D	-	-	-	300	-	-	-	50Mg	-	50Mg	-	-	2	1	2	4	6	7	3
38	1148438	RS	-	-	-	180	-	-	-	-	-	-	-	-	-	1	2	2	1	2	1
39	1230235	RKG	-	-	-	240	-	-	-	-	50 Mg	-	-	-	1	0	1	2	1	2	1

S. No.	MRD NO.	Name	RESCUE DOSE OF FENTANYL ADMINISTERED										SEDATION SCORE								URIN		
			5 hours	6 hours	After shifting to PACU (0min)	30 min	1 hour	2 hours	3 hours	4 hours	5 hours	6 hours	After shifting to PACU(0min)	30 min	1 hour	2 hours	3 hours	4 hours	5 hours	6 hours	After shifting to PACU(0min)	30 min	1 hour
1	935117	JS	1	1	-	-	-	-	-	-	-	-	5	6	6	4	3	2	3	4	100	250	320
2	1114286	SS	1	1	-	-	-	50mcg	-	-	-	-	5	6	6	4	3	3	4	5	50	100	150
3	984897	MS	2	2	-	-	-	-	50mcg	-	-	-	4	4	5	6	5	4	5	5	0	30	65
4	1010354	PK	0	0	-	-	-	-	-	-	-	-	5	5	6	6	5	6	5	5	110	200	300
5	1143923	HS	1	0	-	-	50mcg	-	-	-	-	-	5	6	5	4	2	3	3	4	50	120	140
6	1043530	RS	1	0	-	-	5omcg	-	50mcg	-	-	-	5	5	6	4	3	4	4	4	50	120	170
7	1152801	SK	0	0	-	-	-	-	-	-	-	-	5	6	5	4	3	4	4	4	50	120	180
8	1128324	G	0	0	-	-	-	-	-	-	-	-	5	6	5	4	5	5	5	5	50	90	140
9	1144198	HM	0	0	-	-	-	-	-	-	-	-	5	6	6	5	5	5	5	5	180	300	360
10	1146709	RS	1	0	-	-	50mcg	-	50mcg	-	-	-	5	5	4	4	5	3	4	5	0	40	110
11	1162670	SS	0	0	-	-	-	-	-	-	-	-	5	5	6	5	4	5	5	5	100	160	210
12	743693	RK	0	0	-	-	-	-	-	-	-	-	5	5	6	4	5	5	5	5	20	100	150
13	1186766	KK	0	0	-	-	-	-	-	-	-	-	5	5	5	6	5	5	5	5	110	200	260
14	1210051	RS	1	0	-	-	-	50mcg	-	50mcg	-	-	5	5	5	6	5	6	4	5	30	110	160
15	1212547	VK	0	0	-	-	-	-	-	-	-	-	5	6	6	5	4	5	5	5	30	100	160
16	1213674	RS	1	0	-	-	-	-	50mcg	-	-	-	5	5	6	5	5	4	5	5	50	120	200
17	1164802	N	0	0	-	-	-	-	-	-	-	-	5	5	6	4	4	5	5	5	120	200	300
18	1160005	SS	0	0	-	-	-	-	-	-	-	-	5	6	4	5	5	5	5	5	40	110	180
19	1225185	RL	1	0	-	-	-	50mcg	-	-	-	-	5	5	5	6	5	5	5	5	100	140	200
20	1232827	RS	1	0	-	-	-	-	50mcg	-	-	-	5	5	6	6	5	5	5	5	100	160	250
21	1234161	S	0	0	-	-	-	-	-	-	-	-	5	5	6	5	4	5	5	5	100	160	210
22	1175412	JS	0	0	-	-	-	-	-	-	-	-	5	6	6	5	4	5	5	5	80	150	210
23	1235432	S	0	0	-	-	-	-	-	-	-	-	5	6	6	5	4	5	5	5	50	140	210
24	1244401	K	0	0	-	-	-	-	-	-	-	-	5	5	5	5	5	5	5	5	100	140	200
25	1248480	GS	0	0	-	-	-	-	-	-	-	-	5	5	6	4	5	5	5	5	80	160	230
26	4286	WS	2	0	-	-	-	-	50mcg	-	-	-	5	5	6	5	6	5	4	5	50	100	160
27	1128371	GS	0	0	-	-	50mcg	-	-	-	-	-	5	6	6	5	4	5	5	5	80	200	260
28	1188062	HS	0	0	-	-	-	-	-	-	-	-	5	6	4	4	5	5	5	5	50	120	250
29	1268314	G	0	0	-	-	-	50mcg	-	-	-	-	5	6	6	5	4	4	5	5	45	90	140
30	1268919	HR	0	0	-	-	-	-	-	-	-	-	5	6	5	4	5	5	5	5	60	130	200
31	1245051	BK	0	0	-	-	50mcg	-	-	-	-	-	5	5	5	6	5	5	5	5	30	100	180
32	1270911	IS	0	0	-	-	-	-	-	-	-	-	4	4	5	5	6	5	3	4	50	75	120
33	1276386	S	0	0	-	-	-	-	-	-	-	-	5	5	6	5	5	5	5	5	80	130	220
34	1277168	J	1	0	-	-	50mcg	-	-	-	-	-	5	5	5	6	5	5	5	5	30	100	180
35	1277011	KS	0	0	-	-	-	-	-	-	-	-	4	4	5	5	6	5	3	4	50	70	130
36	1248200	DS	2	0	-	-	-	-	50mcg	-	-	-	5	5	6	6	6	5	4	5	20	100	150
37	941549	D	0	0	-	-	-	50mcg	-	-	-	-	5	6	6	5	6	5	5	5	50	110	170
38	1148438	RS	1	1	-	-	-	-	-	-	-	-	5	6	6	4	3	2	3	4	80	150	200
39	1230235	RKG	0	0	-	-	-	-	50mcg	-	-	-	5	5	6	6	6	5	5	5	40	100	130

S. No.	MRD NO.	Name	E OUTPUT(ML)					HEART RATE								SYSTOLIC BLOOD PRESSURE							
			2 hours	3 hours	4 hours	5 hours	6 hours	After shifting to PACU(0min)	30 min	1 hour	2 hours	3 hours	4 hours	5 hours	6 hours	After shifting to PACU(0min)	30 min	1 hour	2 hours	3 hours	4 hours	5 hours	6 hours
1	935117	JS	400	460	550	620	700	80	90	100	96	94	92	85	84	110	120	130	128	126	124	116	114
2	1114286	SS	220	300	360	425	500	95	100	110	105	100	95	90	92	130	140	150	145	142	135	132	125
3	984897	MS	120	200	280	350	450	80	85	90	88	86	84	82	81	120	125	130	128	125	122	115	110
4	1010354	PK	420	500	550	600	700	66	70	72	90	86	80	76	70	120	126	128	140	130	130	126	110
5	1143923	HS	200	260	350	420	490	90	102	110	88	80	76	78	82	120	130	155	118	110	108	112	115
6	1043530	RS	240	300	340	400	480	70	90	110	115	105	98	96	92	110	130	150	160	145	140	130	120
7	1152801	SK	240	300	350	420	500	80	90	100	95	90	85	82	80	120	130	140	135	132	128	125	120
8	1128324	G	180	210	260	310	360	60	72	80	75	70	66	64	62	110	120	130	128	126	124	116	114
9	1144198	HM	450	560	670	780	900	70	72	80	78	70	68	66	68	110	120	130	126	120	110	106	110
10	1146709	RS	160	210	270	320	370	80	85	105	100	98	100	90	82	110	120	130	128	125	130	125	120
11	1162670	SS	300	320	400	460	550	70	76	86	80	70	72	71	68	110	120	130	126	120	116	112	108
12	743693	RK	210	250	300	350	400	65	90	80	78	76	70	68	66	120	130	128	126	120	118	124	122
13	1186766	KK	340	410	520	700	820	72	76	78	80	78	78	74	70	110	112	114	120	118	116	110	110
14	1210051	RS	210	270	320	360	380	80	86	88	100	96	92	90	86	110	120	126	130	128	126	120	118
15	1212547	VK	210	270	320	400	500	90	100	130	110	100	90	86	84	110	130	150	140	126	116	110	106
16	1213674	RS	260	330	410	520	700	70	80	110	116	106	86	76	72	126	140	160	166	150	130	126	120
17	1164802	N	400	520	600	650	730	70	80	100	86	82	76	72	70	116	132	14	136	130	120	118	118
18	1160005	SS	250	320	410	500	600	60	76	72	70	68	66	68	70	110	120	120	116	114	120	110	105
19	1225185	RL	250	320	370	450	500	80	90	110	104	100	96	90	84	100	110	140	130	120	106	102	100
20	1232827	RS	350	420	550	650	800	80	90	100	110	106	90	80	76	120	130	150	150	140	140	120	110
21	1234161	S	280	350	410	500	580	70	80	100	90	80	72	70	62	108	120	130	126	120	110	108	106
22	1175412	JS	280	350	420	500	580	82	90	110	96	90	88	86	80	130	150	170	160	140	140	130	120
23	1235432	S	300	360	440	520	610	70	80	92	90	86	82	80	66	118	130	140	140	136	132	120	110
24	1244401	K	260	300	350	400	500	70	100	80	76	74	72	70	68	118	130	126	120	110	112	110	105
25	1248480	GS	310	400	520	650	800	80	106	96	90	88	86	104	78	110	122	130	130	130	120	120	110
26	4286	WS	220	300	340	410	500	60	66	76	80	78	80	72	62	110	120	130	136	130	138	130	120
27	1128371	GS	400	520	600	700	760	70	90	120	110	100	90	78	76	110	132	152	146	140	130	120	110
28	1188062	HS	300	360	450	520	600	50	66	60	55	52	54	50	52	120	140	130	120	110	116	114	110
29	1268314	G	210	260	320	370	400	60	70	90	84	80	76	70	66	110	120	126	124	122	120	116	110
30	1268919	HR	260	300	380	450	600	66	86	80	76	70	68	66	64	110	140	130	120	110	110	108	100
31	1245051	BK	220	300	360	400	460	90	120	110	104	100	96	90	90	130	150	140	136	132	130	120	126
32	1270911	IS	150	200	260	320	400	80	85	88	94	110	100	90	82	110	118	120	130	140	125	122	115
33	1276386	S	320	450	600	720	860	78	86	96	94	90	86	82	80	120	130	140	140	130	128	120	110
34	1277168	J	220	300	360	400	460	90	120	110	104	100	96	90	90	130	150	140	136	132	130	120	126
35	1277011	KS	160	200	260	320	400	80	85	86	92	110	100	90	82	110	118	120	130	140	125	122	115
36	1248200	DS	180	250	300	400	500	80	85	100	95	105	90	80	75	130	136	150	140	146	140	136	120
37	941549	D	200	250	320	400	460	80	85	100	120	110	90	86	82	110	120	130	140	130	126	120	110
38	1148438	RS	30	350	400	450	500	80	9	100	96	94	92	84	80	110	120	130	128	126	124	116	114
39	1230235	RKG	210	240	280	300	380	60	70	80	76	72	72	70	68	110	120	130	126	124	120	118	116

S. No.	MRD NO.	Name	DIASTOLIC BLOOD PRESSURE								MEAN ARTERIAL PRESSURE								RESPIRATORY			
			After shifting to PACU(0min)	30 min	1 hour	2 hours	3 hours	4 hours	5 hours	6 hours	After shifting to PACU(0min)	30 min	1 hour	2 hours	3 hours	4 hours	5 hours	6 hours	After shifting to PACU(0min)	30 min	1 hour	2 hours
1	935117	JS	70	75	78	76	75	72	70	68	83	90	95	93	92	89	85	83	18	20	18	17
2	1114286	SS	70	80	90	85	82	75	72	65	90	100	110	105	102	95	92	85	18	20	18	17
3	984897	MS	85	82	85	84	82	80	75	72	97	96	100	99	96	94	88	85	18	18	18	17
4	1010354	PK	70	70	60	90	80	76	76	70	87	89	83	107	97	94	93	83	16	16	18	18
5	1143923	HS	70	85	90	68	60	59	62	65	87	100	112	85	77	75	79	82	18	20	22	21
6	1043530	RS	72	85	90	100	85	80	70	80	85	100	110	120	105	100	90	93	18	20	22	24
7	1152801	SK	80	70	80	75	72	70	68	70	93	90	100	95	92	89	87	87	18	20	22	20
8	1128324	G	70	75	80	76	74	72	70	68	83	90	96	93	92	89	85	83	18	20	18	17
9	1144198	HM	70	80	70	70	70	82	60	60	83	93	90	89	87	91	75	77	16	18	20	20
10	1146709	RS	70	75	70	68	65	70	75	70	83	90	90	88	85	90	92	87	18	18	20	22
11	1162670	SS	70	70	76	70	80	80	68	70	83	87	94	89	93	92	83	83	14	16	18	16
12	743693	RK	80	70	68	66	60	70	76	78	93	90	88	86	80	86	92	93	18	20	22	20
13	1186766	KK	62	66	70	72	70	64	60	58	78	81	85	88	86	81	77	75	16	18	18	20
14	1210051	RS	60	70	80	90	82	80	76	60	77	87	95	103	97	95	91	79	14	16	16	18
15	1212547	VK	70	80	100	70	80	76	70	60	83	97	117	93	95	89	83	75	14	18	20	18
16	1213674	RS	70	70	90	96	100	70	72	60	89	93	113	119	117	90	90	80	16	18	20	22
17	1164802	N	70	90	96	90	90	70	66	70	85	104	111	105	103	87	83	86	16	18	20	18
18	1160005	SS	70	72	68	70	72	62	66	70	83	88	85	85	86	81	82	82	16	18	16	16
19	1225185	RL	60	65	80	70	68	62	60	60	73	80	100	90	85	77	74	73	14	16	18	16
20	1232827	RS	70	80	90	100	90	80	85	70	87	97	110	117	107	100	97	83	16	18	20	20
21	1234161	S	60	65	70	70	66	70	68	62	76	83	90	89	84	83	81	77	16	18	20	18
22	1175412	JS	70	80	80	70	90	82	76	80	90	103	110	100	107	101	94	93	16	18	20	20
23	1235432	S	76	92	96	90	90	70	80	76	90	105	111	107	105	91	93	87	16	18	18	16
24	1244401	K	70	80	80	72	76	70	66	60	86	97	95	88	87	84	81	75	16	18	17	18
25	1248480	GS	76	80	90	82	70	86	76	56	87	94	103	98	90	97	91	74	16	18	20	18
26	4286	WS	70	70	68	76	80	78	70	70	83	87	89	96	97	98	90	87	16	17	18	20
27	1128371	GS	60	70	76	72	70	76	70	50	77	91	101	97	93	94	87	70	16	18	20	19
28	1188062	HS	70	76	76	60	50	56	54	56	87	97	94	80	70	76	74	74	16	20	18	16
29	1268314	G	70	70	72	70	66	70	70	72	83	87	90	88	85	87	85	85	16	16	18	18
30	1268919	HR	70	80	76	80	80	76	70	60	83	100	94	93	90	87	83	73	16	20	18	18
31	1245051	BK	80	90	86	84	80	86	70	68	97	110	104	101	97	101	87	82	16	18	18	18
32	1270911	IS	70	80	82	86	90	4	83	70	83	93	95	101	107	98	96	85	16	16	18	20
33	1276386	S	70	74	86	80	82	78	86	70	87	93	104	100	98	95	97	83	16	18	20	18
34	1277168	J	80	90	86	84	80	86	70	68	97	110	104	101	97	101	87	87	16	18	18	18
35	1277011	KS	70	80	82	86	90	84	83	70	83	93	95	101	107	98	96	85	14	14	16	20
36	1248200	DS	85	90	100	95	98	90	86	70	100	105	117	110	114	107	103	87	14	16	18	18
37	941549	D	70	70	76	80	90	70	76	60	83	87	94	100	103	89	91	77	16	17	18	20
38	1148438	RS	70	75	78	76	75	72	70	68	83	90	95	93	89	85	85	83	18	20	18	17
39	1230235	RKG	70	70	80	80	76	72	70	68	83	87	97	95	92	88	86	84	16	18	18	18

S. No.	MRD NO.	Name	RATE				OXYGEN SATURATION								ADVERSE EFFECT				
			3 hours	4 hours	5 hours	6 hours	After shifting to PACU(0min)	30 min	1 hour	2 hours	3 hours	4 hours	5 hours	6 hours	NAME OF ADVERSE EFFECT	TIME OF ADVERSE EFFECT	NO OF EPISODES	TREATMENT ADMINSTERED	RECOVERED OR NOT
1	935117	JS	16	16	17	16	97	98	97	96	98	97	96	97	-	-	-	-	-
2	1114286	SS	16	18	17	16	98	97	98	98	98	97	98	97	-	-	-	-	-
3	984897	MS	16	16	17	16	98	97	98	97	96	97	96	95	-	-	-	-	-
4	1010354	PK	16	14	16	14	97	98	97	96	97	96	97	96	-	-	-	-	-
5	1143923	HS	18	17	16	16	97	98	99	97	96	97	96	98	-	-	-	-	-
6	1043530	RS	21	19	18	16	97	96	98	95	94	96	97	98	-	-	-	-	-
7	1152801	SK	18	16	16	16	97	98	98	97	98	98	98	98	-	-	-	-	-
8	1128324	G	16	16	17	16	97	98	97	96	98	97	96	97	-	-	-	-	-
9	1144198	HM	18	18	16	16	96	97	98	99	98	98	99	99	Dizziness	11:00AM	1	-	Recovered
10	1146709	RS	18	20	18	18	98	97	98	97	98	96	97	98	-	-	-	-	-
11	1162670	SS	16	14	16	14	97	98	97	98	97	98	98	97	-	-	-	-	-
12	743693	RK	18	20	18	18	97	98	98	97	98	96	97	98	-	-	-	-	-
13	1186766	KK	18	16	16	16	97	98	97	98	99	99	98	98	-	-	-	-	-
14	1210051	RS	16	16	14	14	97	98	97	98	98	98	97	98	Blurred Vision	2:00PM	1	-	Recovered
15	1212547	VK	16	16	14	14	97	98	98	97	98	97	97	97	-	-	-	-	-
16	1213674	RS	20	18	16	14	97	98	97	99	97	98	99	99	Dry Mouth	1:40PM	1	-	Recovered
17	1164802	N	18	16	16	16	97	98	97	99	98	97	98	98	-	-	-	-	-
18	1160005	SS	18	14	14	16	97	98	99	96	98	99	99	98	-	-	-	-	-
19	1225185	RL	16	14	16	14	97	98	97	98	97	98	97	97	-	-	-	-	-
20	1232827	RS	18	17	16	16	98	99	98	97	98	99	97	97	-	-	-	-	-
21	1234161	S	16	17	16	16	97	98	97	96	97	98	97	97	-	-	-	-	-
22	1175412	JS	18	18	16	16	97	98	98	99	97	98	99	99	-	-	-	-	-
23	1235432	S	16	14	16	14	97	98	97	96	97	98	99	99	Dizziness	11:00AM	1	-	Recovered
24	1244401	K	17	16	16	16	97	98	97	96	96	97	98	99	-	-	-	-	-
25	1248480	GS	16	16	16	14	97	98	96	99	97	98	99	99	Tachycardia	3:50PM	1	-	Recovered
26	4286	WS	18	20	18	16	97	98	98	97	98	98	98	98	Blurred Vision	1:10PM	1	-	Recovered
27	1128371	GS	17	16	16	16	97	98	98	97	98	96	97	98	-	-	-	-	-
28	1188062	HS	14	16	16	14	97	98	97	98	97	98	98	98	-	-	-	-	-
29	1268314	G	16	16	16	14	97	98	99	98	97	98	97	98	-	-	-	-	-
30	1268919	HR	16	16	18	16	97	98	97	96	97	98	98	98	-	-	-	-	-
31	1245051	BK	20	16	16	14	97	98	97	97	96	97	96	95	Tachycardia	11:00AM	1	-	Recovered
32	1270911	IS	22	20	18	16	97	98	97	98	97	98	97	98	-	-	-	-	-
33	1276386	S	18	18	16	16	97	98	100	98	99	99	100	99	Dry Mouth	12:00PM	1	-	Recovered
34	1277168	J	20	18	16	14	97	98	97	97	96	97	96	95	-	-	-	-	-
35	1277011	KS	22	20	18	16	98	98	98	98	97	98	98	99	-	-	-	-	-
36	1248200	DS	20	18	16	14	97	98	97	98	99	98	97	98	Tachycardia	5:00PM	1	-	Recovered
37	941549	D	18	18	16	14	96	97	98	98	97	96	97	98	Tachycardia	4:00PM	1	-	Recovered
38	1148438	RS	16	17	17	16	97	98	97	96	97	96	96	97	-	-	-	-	-
39	1230235	RKG	16	16	16	14	96	97	98	97	98	97	97	98	-	-	-	-	-

S. No.	MRD NO.	Name	Age(Years)	Diagnosis	Surgery Performed	Height(Feet)	Weight(kg)	BMI	ASA	Anaesthesia Start : Date/Time
40	783226	SS	36	Mesial Temporal Sclerosis	Removal of Epileptic Foci	5 feet 8 inches	70	23.5	2	30-03-2022 8:00am
41	1222616	BS	44	P/0/C/0 Decompressive craniectomy	Cranioplasty	5 feet 8 inches	85	28.5	1	30-03-2022 8:50am
42	1278229	HS	39	L3-4-5 PIVD	Laminectomy & Dissectomy	5 feet 11 inches	110	33.8	2	30-03-2022 9:00am
43	1279290	JS	30	L3 Schwanoma	Excision	6 feet	90	26.9	1	31-03-2022 9:00am
44	1279937	NS	48	Shoulder Dislocation	Latarjet Procedure	5 feet 9 inches	82	27.7	1	1-04-2022 11:00am
45	301433	MS	39	Clavicle fracture	ORIF	5 feet 10 inches	70	22.1	1	4-04-2022 10:00am
46	1283165	PS	39	Cervical spondylosis	Laminectomy & Dissectomy	5 feet 8 inches	86	28.8	2	8-04-2022 9:00am
47	1240023	SS	25	P/0/C/0 Decompressive craniectomy	Cranioplasty	5 feet 8 inches	82	27.5	1	19-04-2022 1:00pm
48	1218923	SS	29	P/0/C/0 Decompressive craniectomy	Cranioplasty	5 feet 10 inches	86	27.2	1	19-04-2022 10:30am
49	1289901	HS	27	Depressed fracture	Elevation	6 feet	100	29.9	2	20-04-2022 9:00am
50	1283759	RK	45	Right Frontal Depressed fracture	Elevation	5 feet 10 inches	90	28.5	2	20-04-2022 9:00am
51	1290616	JS	54	Cervical Myelopathy	Laminectomy & Dissectomy	5 feet 9 inches	87	28.3	2	23-04-2022 9:30am
52	129305	BS	55	Left Parietal Space Occuping Lesion	Excision	5 feet 11 inches	92	28.3	1	23-04-2022 10:00am
53	1273582	GS	45	Flame Burns	Free Flap	5 feet 10 inches	90	28.5	2	07-05-2022 10:00am
54	614117	MS	29	Deviated Nasal Septum	Septoturbinoplasty	6 feet	82	24.5	1	07-05-2022 10:00am
55	1296668	HS	30	Clavicle fracture	Plating	5 feet 10 inches	85	26.9	2	09-05-2022 12:00pm
56	731754	MS	35	L4 L5 PIVD	Laminectomy & Dissectomy	6 feet	96	28.7	1	17-05-2022 9:00am
57	1305947	JS	26	Fracture distal Tibia and Distal End of Radius	External fixator Application	5 feet 10 inches	88	27.8	1	18-05-2022 1:00pm
58	1220883	SS	28	P/0/C/0 Decompressive craniectomy	Cranioplasty	5 feet 7 inches	76	26.2	1	21-05-2022 12:00pm
59	1305952	AK	46	Right Frontal Space occuping lesion	Excision	5 feet 10 inches	90	28.5	2	23-05-2022 9:00am
60	1306710	GS	28	L4 L5 S1 PIVD	Laminectomy & Dissectomy	6 feet	96	28.7	1	25-05-2022 10:00am

S. No.	MRD NO.	Name	Urinary Catheter insertion Date/Time	Surgery Start:Date/Time	Surgery Finish : Date/Time	Anaesthesia finish: Date/Time	Date/Time of Shifting to PACU	Grade of CRBD							
								After shifting to PACU(0min)	30 min	1 hour	2 hours	3 hours	4 hours	5 hours	6 hours
40	783226	SS	30-03-2022 8:05am	30-03-2022 8:10am	30-03-2022 3:00pm	30-03-2022 3:10pm	30-03-2022 3:15pm	0	0	0	1	2	2	1	0
41	1222616	BS	30-03-2022 9:00am	30-03-2022 9:10am	30-03-2022 11:30am	0-03-2022 11:40am	0-03-2022 11:50am	0	1	2	2	1	1	0	0
42	1278229	HS	30-03-2022 9:05am	30-03-2022 9:10am	30-03-2022 2:15pm	30-03-2022 2:20pm	30-03-2022 2:30pm	0	1	2	1	0	0	0	0
43	1279290	JS	31-03-2022 9:05am	31-03-2022 9:15am	31-03-2022 2:00pm	31-03-2022 2:10pm	31-03-2022 2:30pm	0	3	2	1	0	0	0	0
44	1279937	NS	1-04-2022 11:05am	1-04-2022 11:10am	1-04-2022 2:00pm	1-04-2022 2:05pm	1-04-2022 2:10pm	1	2	1	0	0	0	0	0
45	301433	MS	4-04-2022 10:10am	4-04-2022 10:20am	4-04-2022 2:30pm	4-04-2022 2:40pm	4-04-2022 2:50pm	0	0	1	2	2	1	1	0
46	1283165	PS	8-04-2022 9:10am	8-04-2022 9:20am	8-04-2022 1:30pm	8-04-2022 1:35pm	8-04-2022 1:40pm	0	1	3	2	2	2	1	0
47	1240023	SS	19-04-2022 1:05pm	19-04-2022 1:10pm	19-04-2022 4:00pm	19-04-2022 4:10pm	19-04-2022 4:20pm	0	3	1	0	0	0	0	0
48	1218923	SS	19-04-2022 10:40am	19-04-2022 10:50am	19-04-2022 1:00pm	19-04-2022 1:10pm	19-04-2022 1:20pm	0	1	1	2	0	0	0	0
49	1289901	HS	20-04-2022 9:05am	20-04-2022 9:10am	20-04-2022 12:00pm	20-04-2022 12:10pm	20-04-2022 12:20pm	0	3	2	2	2	1	0	0
50	1283759	RK	20-04-2022 9:10am	20-04-2022 9:20am	20-04-2022 12:00pm	20-04-2022 12:10pm	20-04-2022 12:20pm	0	1	3	1	0	0	0	0
51	1290616	JS	23-04-2022 9:40am	23-04-2022 9:50am	23-04-2022 2:00pm	23-04-2022 2:15pm	23-04-2022 2:30pm	0	1	2	1	0	0	0	0
52	129305	BS	23-04-2022 10:10am	23-04-2022 10:20am	23-04-2022 2:30pm	23-04-2022 2:40pm	23-04-2022 3:00pm	0	1	1	2	1	0	0	0
53	1273582	GS	07-05-2022 10:10am	07-05-2022 10:20am	07-05-2022 12:30pm	07-05-2022 12:40pm	07-05-2022 12:45pm	0	1	2	2	2	2	1	0
54	614117	MS	07-05-2022 10:10am	07-05-2022 10:15am	07-05-2022 1:00pm	07-05-2022 1:10pm	07-05-2022 1:15pm	0	2	1	0	0	0	0	0
55	1296668	HS	09-05-2022 12:10pm	09-05-2022 12:15pm	09-05-2022 2:10pm	09-05-2022 2:20pm	09-05-2022 2:30pm	0	2	3	1	0	0	0	0
56	731754	MS	17-05-2022 9:10am	17-05-2022 9:20am	17-05-2022 12:45pm	17-05-2022 1:00pm	17-05-2022 1:15pm	1	2	1	1	1	0	0	0
57	1305947	JS	18-05-2022 1:10pm	18-05-2022 1:20pm	18-05-2022 4:00pm	18-05-2022 4:10pm	18-05-2022 4:20pm	0	1	3	2	2	1	1	0
58	1220883	SS	21-05-2022 12:05pm	21-05-2022 12:10pm	21-05-2022 2:00pm	21-05-2022 2:10pm	21-05-2022 2:20pm	0	1	2	1	1	0	0	0
59	1305952	AK	23-05-2022 9:10am	23-05-2022 9:20am	23-05-2022 1:00pm	23-05-2022 1:10pm	23-05-2022 1:15pm	0	1	3	2	2	1	0	0
60	1306710	GS	25-05-2022 10:10am	25-05-2022 10:20am	25-05-2022 2:00pm	25-05-2022 2:05pm	25-05-2022 2:20pm	0	1	3	1	0	0	0	0

S. No.	MRD NO.	Name	NRS for pain related to CRBD								Treatment administered				
			After shifting to PACU(0min)	30 min	1 hour	2 hours	3 hours	4 hours	5 hours	6 hours	After shifting to PACU(0min)	30 min	1 hour	2 hours	3 hours
40	783226	SS	0	0	0	1	4	4	2	0	-	-	-	-	Hyoscine 20 Mg
41	1222616	BS	0	2	4	5	3	1	0	0	-	-	Hyoscine 20Mg	-	-
42	1278229	HS	0	2	5	3	1	0	0	0	-	-	Pheniramine 22.75Mg	-	-
43	1279290	JS	0	8	6	2	1	0	0	0	-	Pheniramine 22.75Mg	-	-	-
44	1279937	NS	2	5	3	1	0	0	0	0	-	Pheniramine 22.75Mg	-	-	-
45	301433	MS	0	0	2	5	4	3	2	0	-	-	-	Hyoscine 20Mg	-
46	1283165	PS	0	2	7	4	5	4	2	0	-	-	Hyoscine 20Mg	-	-
47	1240023	SS	0	6	2	1	0	0	0	0	-	Pheniramine 22.75Mg	-	-	-
48	1218923	SS	0	2	3	5	1	0	0	0	-	-	-	Pheniramine 22.75Mg	-
49	1289901	HS	1	7	6	5	4	2	1	0	-	Hyoscine 20Mg	-	-	-
50	1283759	RK	0	2	6	1	0	0	0	0	-	-	Pheniramine 22.75Mg	-	-
51	1290616	JS	0	2	4	2	1	0	0	0	-	-	Hyoscine 20Mg	-	-
52	129305	BS	0	2	2	4	2	0	0	0	-	-	-	Hyoscine 20Mg	-
53	1273582	GS	0	2	4	4	5	4	2	0	-	-	Hyoscine 20 Mg	-	-
54	614117	MS	0	4	2	1	0	0	0	0	-	Pheniramine 22.75Mg	-	-	-
55	1296668	HS	0	4	6	3	1	0	0	0	-	Pheniramine 22.75Mg	-	-	-
56	731754	MS	2	4	3	2	1	0	0	0	-	Hyoscine 20Mg	-	-	-
57	1305947	JS	0	2	7	5	4	3	1	0	-	-	Hyoscine 20Mg	-	-
58	1220883	SS	0	2	4	2	1	0	0	0	-	-	Hyoscine 20Mg	-	-
59	1305952	AK	0	2	6	4	4	2	1	0	-	-	Hyoscine 20Mg	-	-
60	1306710	GS	0	2	7	3	0	0	0	0	-	-	Pheniramine 22.75Mg	-	-

S. No.	MRD NO.	Name				Time taken for resolution of CRBD(min)	Rescue dose of Tramadol for CRBD								Frequency of Tramadol administration	NRS for pain at surgical site					
			4 hours	5 hours	6 hours		After shifting to PACU(0min)	30 min	1 hour	2hours	3 hours	4 hours	5 hours	6 hours		After shifting to PACU (0min)	30 min	1 hour	2 hours	3 hours	4 hours
40	783226	SS	-	-	-	120	-	-	-	-	-	-	-	-	-	0	2	1	2	1	1
41	1222616	BS	-	-	-	120	-	-	-	-	-	-	-	-	-	0	1	2	4	2	1
42	1278229	HS	-	-	-	60	-	-	-	-	-	-	-	-	-	0	0	1	0	0	0
43	1279290	JS	-	-	-	90	-	-	-	-	-	-	-	-	-	0	2	1	1	0	2
44	1279937	NS	-	-	-	30	-	-	-	-	-	-	-	-	-	0	0	0	0	0	0
45	301433	MS	-	-	-	120	-	-	-	-	50Mg	-	-	-	1	0	0	0	0	0	0
46	1283165	PS	-	-	-	240	-	-	-	-	50Mg	-	50Mg	-	2	0	1	3	5	3	1
47	1240023	SS	-	-	-	30	-	-	-	-	-	-	-	-	-	0	0	0	0	0	0
48	1218923	SS	-	-	-	60	-	-	-	-	-	-	-	-	-	0	0	0	1	0	0
49	1289901	HS	-	-	-	210	-	-	-	-	50Mg	-	50Mg	-	2	0	0	0	0	0	0
50	1283759	RK	-	-	-	60	-	-	-	-	-	-	-	-	-	0	0	0	1	0	0
51	1290616	JS	-	-	-	60	-	-	-	-	-	-	-	-	-	0	0	0	0	0	0
52	129305	BS	-	-	-	60	-	-	-	-	-	-	-	-	-	0	0	0	1	0	0
53	1273582	GS	-	-	-	240	-	-	-	-	50Mg	-	-	-	1	0	2	3	4	3	1
54	614117	MS	-	-	-	30	-	-	-	-	-	-	-	-	-	0	0	0	0	0	0
55	1296668	HS	-	-	-	90	-	-	-	-	-	-	-	-	-	0	0	0	0	0	0
56	731754	MS	-	-	-	30	-	-	-	50Mg	-	-	-	-	1	0	1	0	0	0	0
57	1305947	JS	-	-	-	180	-	-	-	50Mg	-	50Mg	-	-	2	0	2	3	4	2	1
58	1220883	SS	-	-	-	60	-	-	-	-	50Mg	-	-	-	1	0	0	0	0	0	0
59	1305952	AK	-	-	-	180	-	-	-	-	50Mg	-	-	-	1	0	1	3	4	2	1
60	1306710	GS	-	-	-	60	-	-	-	-	-	-	-	-	-	0	0	1	0	0	0

S. No.	MRD NO.	Name	RESCUE DOSE OF FENTANYL ADMINISTERED										SEDATION SCORE								URIN		
			5 hours	6 hours	After shifting to PACU (0min)	30 min	1 hour	2 hours	3 hours	4 hours	5 hours	6 hours	After shifting to PACU(0min)	30 min	1 hour	2 hours	3 hours	4 hours	5 hours	6 hours	After shifting to PACU(0min)	30 min	1 hour
40	783226	SS	0	0	-	-	-	-	-	-	-	-	5	5	5	5	6	6	5	5	50	100	150
41	1222616	BS	0	0	-	-	-	-	50mcg	-	-	-	5	5	6	5	4	5	5	5	50	100	120
42	1278229	HS	0	0	-	-	-	-	-	-	-	-	5	6	6	5	4	5	5	5	80	120	200
43	1279290	JS	4	0	-	-	-	-	-	-	50mcg	-	5	6	5	5	4	5	6	5	20	100	150
44	1279937	NS	0	0	-	-	-	-	-	-	-	-	6	6	6	5	5	4	5	5	30	100	160
45	301433	MS	0	0	-	-	-	-	-	-	-	-	5	5	6	6	5	5	5	5	50	100	150
46	1283165	PS	0	0	-	-	-	50mcg	-	-	-	-	5	5	6	6	5	5	5	5	80	150	230
47	1240023	SS	0	0	-	-	-	-	-	-	-	-	5	6	5	4	5	5	5	5	80	170	250
48	1218923	SS	0	0	-	-	-	-	-	-	-	-	5	5	6	6	5	4	5	5	80	180	300
49	1289901	HS	0	0	-	-	-	-	-	-	-	-	5	6	6	6	5	5	5	5	80	200	260
50	1283759	RK	0	0	-	-	-	-	-	-	-	-	5	6	6	4	5	5	5	5	100	160	230
51	1290616	JS	0	0	-	-	-	-	-	-	-	-	5	6	6	5	5	5	5	5	75	155	220
52	129305	BS	0	0	-	-	-	-	-	-	-	-	5	5	5	6	5	5	5	5	70	200	280
53	1273582	GS	0	0	-	-	-	50mcg	-	-	-	-	5	6	6	6	4	5	5	5	60	130	210
54	614117	MS	0	0	-	-	-	-	-	-	-	-	5	6	5	5	5	5	5	5	60	150	250
55	1296668	HS	0	0	-	-	-	-	-	-	-	-	5	6	6	5	4	5	5	5	80	160	220
56	731754	MS	0	0	-	-	-	-	-	-	-	-	5	6	5	5	5	5	5	5	100	160	220
57	1305947	JS	0	0	-	-	-	50mcg	-	-	-	-	5	6	6	6	5	5	5	5	70	150	210
58	1220883	SS	0	0	-	-	-	-	-	-	-	-	5	5	6	5	5	5	5	5	60	140	210
59	1305952	AK	0	0	-	-	-	-	50mcg	-	-	-	5	5	6	6	6	5	5	5	110	200	280
60	1306710	GS	0	0	-	-	-	-	-	-	-	-	5	6	6	5	4	5	5	5	120	250	360

S. No.	MRD NO.	Name	E OUTPUT(ML)					HEART RATE								SYSTOLIC BLOOD PRESSURE							
			2 hours	3 hours	4 hours	5 hours	6 hours	After shifting to PACU(0min)	30 min	1 hour	2 hours	3 hours	4 hours	5 hours	6 hours	After shifting to PACU(0min)	30 min	1 hour	2 hours	3 hours	4 hours	5 hours	6 hours
40	783226	SS	210	250	200	340	380	100	105	106	110	120	116	112	102	130	140	150	152	146	142	140	130
41	1222616	BS	200	260	300	340	380	70	76	82	85	80	76	70	66	110	120	130	140	136	130	126	118
42	1278229	HS	240	300	360	400	500	80	85	90	86	82	70	82	76	120	130	140	135	130	125	122	120
43	1279290	JS	200	270	320	400	460	80	110	100	96	90	92	96	90	130	160	140	140	138	136	130	120
44	1279937	NS	210	260	300	320	360	55	70	72	66	58	55	53	56	110	130	126	120	110	106	112	110
45	301433	MS	200	300	400	500	600	80	85	90	100	90	85	80	76	120	130	140	150	140	136	130	120
46	1283165	PS	310	40	480	540	620	70	80	100	96	90	82	70	68	120	126	140	150	140	136	130	120
47	1240023	SS	330	410	500	560	620	70	90	86	84	80	78	76	72	110	120	116	110	112	114	110	100
48	1218923	SS	360	450	520	610	740	90	96	102	110	100	98	90	86	120	130	140	146	138	130	120	110
49	1289901	HS	310	380	450	530	600	68	90	76	80	74	70	68	60	110	160	130	150	126	120	110	110
50	1283759	RK	300	360	420	480	550	62	66	80	76	68	60	62	60	110	120	130	126	120	110	106	110
51	1290616	JS	300	380	450	520	590	76	92	102	94	86	80	76	72	110	140	142	135	130	132	120	110
52	129305	BS	360	470	600	720	900	70	82	90	102	92	86	80	76	110	120	126	140	130	130	120	120
53	1273582	GS	300	380	460	520	600	70	80	90	92	96	90	86	80	110	120	130	136	140	140	130	120
54	614117	MS	340	420	520	600	700	80	90	86	84	80	78	80	76	120	130	140	130	120	122	110	112
55	1296668	HS	300	390	500	560	660	72	80	96	80	70	68	66	68	112	120	130	130	120	116	114	120
56	731754	MS	31	400	520	600	660	70	82	80	76	72	70	68	70	120	130	140	130	120	120	120	110
57	1305947	JS	280	360	420	500	560	72	82	90	88	86	84	80	76	112	116	126	124	120	122	116	112
58	1220883	SS	290	360	440	510	600	70	76	82	80	78	76	74	72	110	114	120	118	116	110	110	108
59	1305952	AK	360	480	590	700	810	70	80	90	86	80	78	80	72	110	130	140	140	130	126	124	120
60	1306710	GS	450	560	670	800	950	80	90	110	90	82	85	80	78	110	120	130	128	120	118	110	106

S. No.	MRD NO.	Name	DIASTOLIC BLOOD PRESSURE								MEAN ARTERIAL PRESSURE								RESPIRATORY			
			After shifting to PACU(0min)	30 min	1 hour	2 hours	3 hours	4 hours	5 hours	6 hours	After shifting to PACU(0min)	30 min	1 hour	2 hours	3 hours	4 hours	5 hours	6 hours	After shifting to PACU(0min)	30 min	1 hour	2 hours
40	783226	SS	70	72	76	80	72	70	72	70	90	95	101	104	97	94	95	90	16	18	20	20
41	1222616	BS	70	76	80	86	84	82	80	78	83	91	97	104	101	98	95	91	16	18	18	18
42	1278229	HS	70	80	90	90	82	70	70	70	87	97	107	105	98	88	87	87	16	17	18	18
43	1279290	JS	70	90	84	86	82	80	76	70	90	113	103	104	101	99	94	87	16	20	18	18
44	1279937	NS	70	70	72	66	76	70	70	70	83	90	90	84	87	82	84	83	16	18	18	16
45	301433	MS	80	86	90	96	92	92	90	70	93	101	107	114	108	107	103	87	16	18	18	18
46	1283165	PS	66	70	82	80	72	70	68	60	84	89	101	103	95	92	89	80	16	18	20	18
47	1240023	SS	70	82	90	82	8	7	66	60	83	95	99	91	91	85	81	73	16	18	20	18
48	1218923	SS	74	78	84	86	80	90	86	80	89	95	103	106	99	103	97	90	16	16	18	20
49	1289901	HS	70	70	70	90	70	70	70	60	83	100	90	110	89	87	83	91	16	20	18	19
50	1283759	RK	70	80	70	7	70	82	60	60	83	93	90	89	87	91	75	77	16	18	20	18
51	1290616	JS	68	70	90	86	90	86	78	76	82	93	107	102	103	101	92	87	16	18	18	20
52	129305	BS	72	80	90	92	86	80	70	80	85	93	102	108	101	97	87	93	16	18	18	20
53	1273582	GS	62	60	66	80	90	86	90	70	78	80	87	99	107	104	103	87	16	18	20	20
54	614117	MS	60	70	76	80	80	70	80	70	80	90	97	97	93	87	90	84	16	18	20	18
55	1296668	HS	72	76	90	86	90	86	80	72	85	91	103	101	100	96	91	88	16	18	20	18
56	731754	MS	82	90	80	80	76	72	70	76	95	103	100	97	91	88	87	87	16	18	18	16
57	1305947	JS	70	72	78	76	80	70	70	66	84	87	94	92	93	87	85	81	16	18	20	18
58	1220883	SS	62	64	76	74	70	68	60	54	78	81	91	89	85	82	77	72	16	18	20	18
59	1305952	AK	76	88	92	82	86	88	80	70	87	102	108	101	101	101	95	87	16	18	20	18
60	1306710	GS	78	85	96	90	70	76	70	72	89	97	107	103	87	90	83	83	16	18	20	18

S. No.	MRD NO.	Name	RATE				OXYGEN SATURATION								ADVERSE EFFECT				
			3 hours	4 hours	5 hours	6 hours	After shifting to PACU(0min)	30 min	1 hour	2 hours	3 hours	4 hours	5 hours	6 hours	NAME OF ADVERSE EFFECT	TIME OF ADVERSE EFFECT	NO OF EPISODES	TREATMENT ADMINSTERED	RECOVERED OR NOT
40	783226	SS	20	18	16	14	98	97	98	97	98	98	98	97	-	-	-	-	-
41	1222616	BS	18	16	14	16	97	98	97	98	97	98	97	98	-	-	-	-	-
42	1278229	HS	17	16	18	17	97	98	97	98	97	96	97	98	-	-	-	-	-
43	1279290	JS	16	16	18	16	97	98	97	98	98	99	99	98	-	-	-	-	-
44	1279937	NS	16	14	16	14	99	98	99	98	99	98	99	99	-	-	-	-	-
45	301433	MS	16	16	16	14	97	98	97	98	97	98	98	99	-	-	-	-	-
46	1283165	PS	18	16	16	14	97	98	98	99	98	99	98	99	Hypertension	11:00AM	1	-	Recovered
47	1240023	SS	18	16	16	16	97	98	99	98	99	99	98	99	-	-	-	-	-
48	1218923	SS	18	18	16	16	97	98	99	98	99	99	98	99	-	-	-	-	-
49	1289901	HS	18	16	14	15	97	98	98	97	98	96	95	98	-	-	-	-	-
50	1283759	RK	20	18	16	14	96	97	97	96	97	96	97	98	-	-	-	-	-
51	1290616	JS	18	16	16	16	97	98	98	99	98	99	98	99	-	-	-	-	-
52	129305	BS	18	18	16	16	97	98	99	98	99	99	98	99	-	-	-	-	-
53	1273582	GS	22	20	16	16	97	98	99	96	97	98	98	99	Hypertension	1:00PM	1	-	Recovered
54	614117	MS	16	16	16	14	97	98	97	98	99	99	97	98	-	-	-	-	-
55	1296668	HS	16	16	16	16	97	98	97	98	99	98	99	99	-	-	-	-	-
56	731754	MS	16	14	16	14	97	98	98	97	98	99	98	99	-	-	-	-	-
57	1305947	JS	18	16	16	16	97	98	99	97	98	99	98	99	-	-	-	-	-
58	1220883	SS	18	16	16	16	97	98	99	98	97	96	99	99	-	-	-	-	-
59	1305952	AK	16	16	14	16	97	98	99	99	98	99	99	99	-	-	-	-	-
60	1306710	GS	16	18	18	16	97	98	99	98	96	97	98	97	-	-	-	-	-

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Date 05/11/22

The Principal,
DMC, Ludhiana.

Subject: Approval of Plan of Thesis.

This is to inform you that the Faculty of Medical Sciences in its meeting held on 29.10.2021 has approved the plan of thesis of **Shubham Garg**, a student of your college for **MD Anaesthesiology** along with the names of Supervisor/Co-Supervisor as under:-

Topic Plan of Thesis

Comparative evaluation of pheniramine versus hyoscine for management of post – operative catheter related bladder discomfort after general anaesthesia.

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The student has to submit the four copies of thesis (along with PDF format) , to the Controller of Examinations, BFUHS, Faridkot, at least six months before the commencement of theory examination, if he/she is otherwise eligible to take the examination. He /She must directed to attach a photocopy of this letter with the forwarding letter while submitting thesis to the University along with the letter of approval of University for change of supervisor/Co-Supervisor, change of topic,(if any).

Dr. S P Singh MS(Oph)
Controller of Examinations

Note :

25. *If any discrepancy found regarding topic of thesis or Supervisor/Co-Supervisor, inform undersigned within one month after issue of this letter.*
26. *The student may submit the thesis as per the schedule already conveyed i.e for May/June examination 30th Nov of the preceding the year of examination and for Nov/Dec examinations 31st May of the year of examination.*

COMPARATIVE EVALUATION OF PHENIRAMINE VERSUS HYOSCINE FOR MANAGEMENT OF POST – OPERATIVE CATHETER RELATED BLADDER DISCOMFORT AFTER GENERAL ANAESTHESIA

THESIS PROPOSAL

FOR APPROVAL OF SUBJECT OF THESIS TO BE SUBMITTED

IN PARTIAL FULFILMENT OF THE REQUIREMENTS

FOR THE DEGREE OF

DOCTOR OF MEDICINE

In

ANAESTHESIOLOGY

OF THE

BABA FARID UNIVERSITY OF HEALTH SCIENCES

FARIDKOT

DECEMBER 2020 **Dr SHUBHAM GARG**

DEPARTMENT OF ANAESTHESIOLOGY
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ABSTRACT OF PLAN OF THESIS

Title	COMPARATIVE EVALUATION OF PHENIRAMINE VERSUS HYOSCINE FOR MANAGEMENT OF POST – OPERATIVE CATHETER RELATED BLADDER DISCOMFORT AFTER GENERAL ANAESTHESIA
For the degree of	M.D. Anaesthesia
Name of the candidate	Dr. Shubham Garg
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Institution	Dayanand Medical College and Hospital, Ludhiana
University	Baba Farid University of Health Sciences, Faridkot

Introduction: Catheter Related Bladder Discomfort (CRBD) is a relatively common complication which is distressing both for the patient and staff in postoperative care unit (PACU). Although various agents are available for prevention as well as management of Catheter Related Bladder Discomfort (CRBD), yet there is no well-established regimen for management of it.

Aim of Study: To compare the efficacy of Pheniramine and Hyoscine in post-operative management of Catheter Related Bladder Discomfort (CRBD) after general anaesthesia.

Materials & Methods: A prospective, double blind, randomized study will be conducted on a total of 60 adult male patients complaining of CRBD in post-operative period who underwent non urological surgeries under general anaesthesia. These patients will be randomly allocated into 2 groups. The technique for general anaesthesia will be standardized in both groups. Group A will receive Injection Pheniramine 22.75 mg IV and group B will receive Injection Hyoscine 20 mg IV.The patients will be observed for 6 hours to compare the severity of CRBD, rescue analgesic requirements and adverse effects

Clinical Significance: Catheter Related Bladder Discomfort (CRBD) above a moderate grade is known to have incidence as high as 38-57%.This study will allow comparison of efficacy of Pheniramine and Hyoscine in its management.

Keywords: Pheniramine, Hyoscine, Urinary Catheterization, Post-operative, Catheter Related Bladder Discomfort (CRBD), General Anaesthesia.

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Candidate	Co-supervisor	Co-supervisor	Supervisor	Principal

CERTIFICATE OF FACILITIES AVAILABLE

This is to certify that the facilities for work on the subject of thesis titled **"COMPARATIVE EVALUATION OF PHENIRAMINE VERSUS HYOSCINE FOR MANAGEMENT OF POST – OPERATIVE CATHETER RELATED BLADDER DISCOMFORT AFTER GENERAL ANAESTHESIA"** exist in the Department of Anaesthesiology at Dayanand Medical College and Hospital, Ludhiana and will be provided to the candidate. We will see that the data being included in the thesis are genuine and is collected by the candidate herself under our supervision and guidance.

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APPROVAL PROFORMA
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PROFORMA FOR REGISTRATION OF SUBJECT FOR DISSERTATION

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3	COURSE OF STUDY AND SUBJECT	M.D. ANAESTHESIOLOGY
4	DATE OF ADMISSION OF COURSE	25TH JULY 2020
5	TITLE OF THE TOPIC	**COMPARATIVE EVALUATION OF PHENIRAMINE VERSUS HYOSCINE FOR MANAGEMENT OF POST –OPERATIVE CATHETER RELATED BLADDER DISCOMFORT AFTER GENERAL ANAESTHESIA**.

6. BRIEF RESUME OF THE INTENDED WORK

6.1 NEED FOR THE STUDY

Urinary bladder catheterization is a commonly performed procedure in peri-operative settings. The insertion of a urinary catheter may result in postoperative Catheter-related bladder discomfort (CRBD).Studies have reported incidence of CRBD to be as high as 47-90 %.[1] The incidence particularly for above a moderate grade CRBD is reported as 38-57%.[2] The symptoms of CRBD are similar to those of overactive bladder (OAB) such as pain and discomfort in the suprapubic region, frequency, urge to void, and a burning sensation with or without urge incontinence.[3,4] These symptoms are usually very distressing to the patient, their relatives, and staff in the postoperative care unit (PACU). Severe CRBD is associated with behavioural responses such as a strong vocal response, flailing extremities, and an attempt to pull out the urinary catheter.[5]

The cause of CRBD is bladder irritation due to muscarinic receptor-mediated involuntary contractions of the bladder smooth muscle resulting in clinical symptoms similar to those of overactive bladder.[6] Since anti-muscarinic drugs are the mainstay of treating OAB, therefore these agents have been employed for prevention and treatment of CRBD too. Thus, drugs such as oxybutynin, tolterodine, and butyl scopolamine have often been used for CRBD.[7-9] Additionally, tramadol, paracetamol and gabapentin administration have been found to be effective for the prevention and treatment of this condition.[4,7,10] Despite availability of these agents, there still is no well-established regimen for the management of CRBD in clinical practice.[5] Hyoscine, an anticholinergic drug, has a high affinity for muscarinic receptors located in the smooth muscle cells of the gastrointestinal (GI) tract and it has been used to treat abdominal cramps and has been effective against CRBD as well.[10] In addition, Hyoscine does not cross the blood–brain barrier because of the attachment of butyl bromide, thus, central adverse effects such as blurred vision and flushing of the face are averted.[11]

Recently, Diphenhydramine – an anti-histaminic agent was found to be effective in prophylaxis of CRBD when administered at the time of induction of anaesthesia.[6,12] Pheniramine is a related drug with similar mechanism of action, more commonly available and widely used agent in clinical practice for management of allergic reactions.[13] It has significant antimuscarinic properties which may be employed for the management of CRBD.

This study has therefore, been designed to evaluate the efficacy of Pheniramine for treatment of post-operative CRBD after general anaesthesia and to compare its effect with Hyoscine.

6.2 REVIEW OF LITERATURE

Urinary catheterization is widely used to avoid bladder retention, allow urine output measurement and blood volume assessment in patients undergoing surgery. A catheter located in the bladder may cause discomfort postoperatively, and this is referred to as Catheter-related bladder discomfort (CRBD). CRBD is more frequent and more severe in the early post-operative period than in late post-operative period. The factors predisposing patient to the occurrence of CRBD include: - age<50 years, male gender, open abdominal surgeries, urinary catheter-related pain ≥ 4, obstetric and gynaecological surgeries. [14]

The mechanism underlying the occurrence of CRBD is the activation of muscarinic acetylcholine receptors by the simulation of the urinary bladder catheter.[15] Yasuhiko highlighted that CRBD is mediated by muscarinic receptors, especially the subtype M_3 receptor.[16]The possible and potential role of urothelial/suburothelial muscarinic receptors in the etiology of detrusor over activity or sensory urgency has been reported by Andersson & Yoshida.[17] Another mechanism underlying the occurrence of catheter-related bladder discomfort is increased urinary concentration of prostaglandin.[10,18]

Antimuscarinic agents are helpful in prevention of CRBD by decreasing both contraction frequency and intensity of bladder through reduction in over activity of detrusor muscles.[19] Bala et al suggested agents with antimuscarinic properties, such as oxybutynin, tolterodine, and butylscopolamine are the mainstay treatment to reduce both the incidence and severity of CRBD.[7-9]Urinary catheter and mucosal injury induces local inflammation with activation of the cyclooxygenase pathway and release of prostaglandins.[20,21] Hence anti-inflammatory agents such as paracetamol and ketorolac are known to be effective in the management of postoperative catheter-related bladder discomfort.[18,20,21] However, although such interventions are done, the incidence of postoperative catheter-related bladder discomfort still varies.[15]

Srivastava(India) et al studied the efficacy of trospium chloride for prevention of CRBD and reported that pre-treatment with 60 mg

extended release trospium reduces the incidence as well as severity of CRBD in early post-operative period.[22] Yunjin Bai(China) reported that anticholinergic agents and antiepileptics (gabapentin and pregabalin) administered 1 hour before surgery reduced the incidence and severity of CRBD in the immediate postoperative period.[5] A randomized controlled trial including patients requiring urinary bladder catheterization for percutaneous nephrolithotomy concluded that intraoperative single-dose paracetamol was effective in reducing the severity of CRBD and pain in urologic surgeries.[10]

Hyoscine an anticholinergic drug is well absorbed from gastrointestinal tract (GIT) and conjunctival membranes. Transdermal route absorption (across the skin) is also observed to be a route of absorption of Hysocine. The usual dose of Hyoscine in gastrointestinal tract (GIT) and genitourinary tract is 0.4 mg TDS [ter die sumendum (to be taken three times daily)] and in ophthalmological conditions it is usually used in concentration of 0.25% and duration of action is 3-7 days.[23] It blocks the action of acetylcholine at parasympathetic sites in smooth muscle, and secretory glands. Both its primary therapeutic effects and its side effects are based on this. Thus it causes decreased motility of the gastrointestinal tract and the urogenital tracts, and is useful in the treatment of spasms as may be seen in gastroenteritis, colitis, inflammatory bowel disease, diverticulitis, biliary colic, cystitis, ureteric colic, and primary dysmenorrhea. It is also used to prevent spasms of the gastrointestinal tract prior to invasive radiologic and diagnostic procedures, such as endoscopic retrograde cholangiopancreatography (ERCP) and colonoscopy. It has been used to treat abdominal cramps and has been found effective against CRBD as well. [11] Treatment with Hyoscine directed at one organ system almost always induces undesirable effects in other organ systems. Thus, mydriasis and cycloplegia are adverse effects when an antimuscarinic agent is used to reduce gastrointestinal secretion or motility, even though they are therapeutic effects when the drug is used in ophthalmology. Recent evidence indicates that some centrally acting drugs [tricyclic

antidepressants (TCA), selective serotonin reuptake inhibitors (SSRIs), anti-anxiety agents] when given with antimuscarinic actions impair memory and cognition in older patients. Hyoscine like another antimuscarinic agents is contraindicated in patients with glaucoma, especially angle-closure glaucoma. Even systemic use of moderate doses may precipitate angle closure (and acute glaucoma) in patients with shallow anterior chambers. In elderly men, it should always be used with caution and should be avoided in those with a history of prostatic hyperplasia. Because it slows gastric emptying, it may increase symptoms in patients with gastric ulcer.[23] Antacids also interfere with absorption of it.[24] Salama et al compared Ketamine vs Hysocine for the post-operative management of catheter related bladder discomfort and concluded that intravenous Hyoscine 20 mg is more effective in control of CRBD than Ketamine 0.25 mg per kg in first 30 minutes and later on they have same effect.[25]

The property of Diphenhydramine to produce antihistamine as well as antimuscarinic effect was used by Yu-Yu Li et al to successfully attenuate postoperative CRBD without significant side effects in patients undergoing gynecologic laparoscopic surgery when given prophylactically.[6] Diphenhydramine is rapidly absorbed after oral administration, with peak blood concentrations occurring in 1–2 hours and is widely distributed throughout the body and enter the central nervous system readily.[26] Sedation, diminished alertness and concentration, light headedness, motor incoordination, fatigue and tendency to fall asleep are the most common side effects of Diphenhydramine and Pheniramine. Objective testing shows impairment of psychomotor performance. Patients should be cautioned not to operate motor vehicles or machinery requiring constant attention. Alcohol synergises in producing these effects as do other CNS depressants. Few individuals become restless, nervous and are unable to sleep. Second generation compounds are largely free of CNS effects. Regular use of these drugs is not advisable in children, because the CNS depressant property may interfere with learning and academic tasks. Dryness of mouth, alteration of bowel movement,

urinary hesitancy and blurring of vision can be ascribed to its anticholinergic property. Epigastric distress and headache may be felt. Local application can cause contact dermatitis.[27] Pheniramine belonging to same antihistamine class can also be used for it. The antihistaminic effect will contribute to sedative effect while the anticholinergic effect will be therapeutic effect for CRBD.

There has been only few studies evaluating role of Hyoscine in CRBD management while Pheniramine has not been studied at all with respect to CRBD .Hence we plan to study and compare the efficacy of Pheniramine and Hyoscine for treatment of post-operative CRBD after general anaesthesia.

6.3 AIMS AND OBJECTIVES OF THE STUDY

To compare the efficacy and safety of Pheniramine and Hyoscine in terms of:

- Management of CRBD.
- Post-operative analgesic requirements.
- Adverse effects.

7. MATERIALS AND METHODS

7.1 SOURCE OF DATA

This study would be conducted in a randomized, double blinded manner. A total of 60 adult male patients aged 25-55 years belonging to ASA grade I and II posted for elective non-urological surgeries under general anaesthesia who would be catheterized and complain of CRBD will be enrolled in the study, after approval from institutional ethics committee (IEC). Written, informed consent would be obtained from all patients.

7.2 METHOD OF COLLECTION OF DATA

Inclusion Criteria

1. Adult male patient between 25-55 years of age posted for elective non- urological surgeries under general anaesthesia.
2. American Society of Anaesthesiologist(ASA) Class I-II.[28]

Exclusion criteria:

Patients would be excluded from this study if they had any of the following:

1. Clinical evidence of previous lower urinary system diseases needing medical or surgical intervention (such as prostate diseases or urethral stricture),
2. History or current evidence of urinary tract infection (UTI).
3. Bladder outlet obstruction, overactive bladder (urination frequency > 3 times/night or > 8 times in 24 h)
4. Patients already on alpha 1 adrenergic antagonists like tamsulosin.
5. Any difficulty or resistance encountered during catheterization.
6. Morbid obesity (body mass index over 40).
7. Chronic renal failure.
8. History of ischemic heart disease, myocardial infarction, hepatic or psychiatric disease.
9. History of substance abuse, chronic pain or gabapentin use.
10. History of neurologic disease like stroke, parkinsonism, alzeihemer's.
11. History of Bronchial asthma or thyroid disease.

12. History of narrow angle glaucoma.
13. Patients with catheter in-situ before shifting to operating room.
14. History of drug allergy to Diclofenac, Pheniramine and Hyoscine.

PRE ANAESTHETIC CHECKUP

All patients will undergo a thorough pre-anaesthesia evaluation. Complete blood count (CBC), renal function tests, random blood glucose levels, prothrombin time (PT), activated partial thromboplastin time (PTTK), electrocardiogram (ECG) and chest X-ray would be performed for all patients. Patients would be informed about the use of Numeric Rating Scale (NRS) as a tool for post-operative pain assessment, and that they can request analgesic at any time if they have pain. They would also be educated to distinguish between post-operative pain at the wound site and CRBD.

ANAESTHESIA TECHNIQUE

All patients will be kept nil per orally for 8 hours prior to surgery and pre-medicated with oral alprazolam 0.5 mg at bed time on the night prior to surgery. In the operating room intravenous (IV) access will be secured. Standard monitoring in the form of Electrocardiogram (ECG), Heart Rate (HR), Arterial Oxygen Saturation (SpO2), Non Invasive Blood Pressure (NIBP) and end tidal carbon dioxide (EtCO2) would be carried out. These parameters will be monitored throughout the procedure and recorded at an interval of 5 minutes. General anaesthesia would be induced with IV midazolam 1 mg, IV fentanyl 2 µg/kg and IV propofol 2 mg/kg. Atracurium 0.5 mg/kg IV would be used to facilitate orotracheal intubation. Anaesthesia would be maintained with 60% N2O in O2 and IV fentanyl 0.5 - 1 mcg/kg as required. The muscular relaxation would be maintained with IV atracurium 5 mg bolus every 15- 20 minutes. Ventilation will be adjusted to maintain $EtCO_2$ between 30 and 40 mm Hg. Isofluarne concentration would be titrated to maintain mean arterial pressure within 20% of pre-anaesthetic levels. Intra-operative management of patient including fluid and additional fentanyl administration would be at the discretion of

anaesthesiologist managing the case as per standard anaesthesia technique.

A 16 French Foley's catheter would be inserted in all patients after adequate lubrication of urethra with lignocaine jelly and the balloon inflated with 10 ml of distilled water. The urinary catheter would be fixed with an adhesive tape without any traction and drained into a urinary bag. All patients will be administered IV diclofenac 75 mg at the beginning of skin closure. On completion of surgery, neuromuscular blockade would be reversed with IV neostigmine 0.5 mg/kg and IV glycopyrrolate 0.01 mg/kg, trachea extubated and patients transferred to the postanesthesia care unit (PACU). Paracetamol and tramadol would not be administered intra-operatively.

The time of shifting of patients to PACU would be labelled as time '0' and patients will be followed up by an anaesthesia resident for symptoms of CRBD for up to 6 hours.

The severity of CRBD would be described as:

Grade 0 – No discomfort reported on questioning.

Grade 1 – Mild discomfort, reported by patient only on questioning.

Grade 2 – Moderate discomfort, reported feeling of urgency of urination without questioning but not accompanied by any behavioural response;

Grade 3– Severe discomfort, reported by patient without asking and accompanied by behavioural responses such as attempts to remove the urinary catheter, restless extremity movements or verbal responses.[29]

Patients complaining of CRBD grade 2 or 3 would be enrolled for the study and randomly allocated to either of two groups on reaching post-operative recovery.

Group A would be administered Injection Pheniramine 22.75 mg IV.

Group B would be administered Injection Hyoscine 20 mg IV.

Both drugs would be diluted with normal saline to make a total volume of 10 ml in identical syringes.

Randomization would be done by computer generated random numbers which would be kept in an opaque sealed envelope. A number inside the envelope would determine the group to which the

patient belongs. The envelope would be opened and study medication prepared by another anaesthesia resident, not involved with the study.

Follow up of patients would be by an anaesthesia resident blinded to the study drugs administered. At each observation interval, post-operative pain as assessed by NRS, Heart rate (HR), Mean blood pressure (MAP), NRS score for CRBD and sedation score of patient would also be recorded. The follow up assessment would be performed at 30 min, 1 hours and every subsequent hour for 6 hours. During each evaluation, the patient would also be asked to determine whether the pain was related to CRBD or to the wound of surgery. Any patient complaining of pain, or reporting NRS ≥4 for pain at surgical site or demanding an analgesic would be administered fentanyl 50 mcg IV. The time of administration of rescue analgesic and NRS at that time would be recorded. Patients still complaining of CRBD grade 2 or 3 at subsequent observation intervals would be managed with rescue dose of tramadol 50 mg, which would be recorded.

Sedation would be evaluated using a modified Observer's Assessment of Alertness/Sedation score (given below) at the each observation time interval.

All patients would be continuously monitored and any episode of bradycardia (defined as Heart rate < 60/ min) or tachycardia (defined as Heart rate > 100/ min) would be noted.

Any episode of hypotension defined as (MAP below 20 % of pre-anaesthetic levels) or hypertension (MAP above 20 % of pre-anaesthetic levels) would also be recorded. These problems would be managed by anaesthesiologist who conducted the case as per department protocol.

OUTCOME

PRIMARY OUTCOME

The primary outcome will be measured as reduction in severity of CRBD.

SECONDARY OUTCOME

The secondary outcome will be measured as dose and frequency of post-operative analgesic (tramadol) used and adverse effects.

STATISTICAL ANALYSIS

The objective of the study is to compare the efficacy of Pheniramine and Hyoscine in post-operative management of Catheter Related Bladder Discomfort (CRBD) after general anaesthesia.

The formula used is as under:

$n = (\sigma 12 + \sigma 22) (Z\alpha + Z\beta)2/(m1 – m2)2$

Where,

$Z\alpha$ = Value of standard normal variate corresponding to α level of significance (1.96)

$Z\beta$ = The standard normal deviate for desired power (1.282)

m = Average

σ = Standard deviation

Assumptions:

From the pilot study conducted ,

Mean Group (m1) = 55

Mean Group (m2) = 40

Coefficient of variation = 150%

Standard deviation Group (σ1) = 21

Standard deviation (σ2) = 12

Change in the parameters (m1– m2) = 15

With the above assumptions the sample size for 95% confidence level & 90% power works out 27 in each group .Assuming 10% drop out , we will include 30 cases in each group.

7.3 DOES THE STUDY REQUIRE ANY INVESTIGATIONS OR INTERVENTIONS TO BE CONDUCTED ON PATIENTS OR OTHER HUMANS OR ANIMALS? IF SO, PLEASE DESCRIBE BRIEFLY.

The study does not require any investigation. An intervention in the form of Hyoscine or Pheniramine will be randomly given to all eligible patients.

7.4 HAS ETHICAL CLEARENCE BEEN OBTAINED FROM YOUR INSTITUTION IN CASE OF 7.3?

Attached alongwith.

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PROFORMA

S.No	Mrd No.
Name	Randomization No.
Age	Diagnosis
Surgery Performed	Height
Weight	BMI
ASA Grade	Anaesthesia start: Date/Time
Urinary Catheter Insertion Date/Time	Surgery start: Date/Time
Surgery finish: Date/Time	Anaesthesia finish: Date/Time
Date/Time of shifting to PACU	

Signature of Candidate

Signature of Supervisor

	After shifting to PACU Time '0'	30 min	1 hour	2 hours	3 hours	4 hours	5 hours	6 hours
Grade of CRBD								
NRS for pain related to CRBD								
Treatment administered								
Rescue dose of tramadol for CRBD								
NRS for pain at surgical site								
Rescue dose of Fentanyl administered								
Sedation score								
Urine Output								

POST-OPERATIVE VITALS

Time of admission to PACU	0 min	30 min	1 hour	2 hour	3 hour	4 hour	5 hour	6 hour
HR								
SBP								
DBP								
MAP								
RR								
SPO2								

Signature of Candidate **Signature of Supervisor**

Adverse effects

Adverse effect	Time of adverse effect	No. of episodes	Treatment administered	Recovered or Not
Nausea/ vomiting				
Blurred vision				
Dizziness				
Dry mouth				
Hypotension				
Hypertension				
Bradycardia				
Tachycardia				
Others				

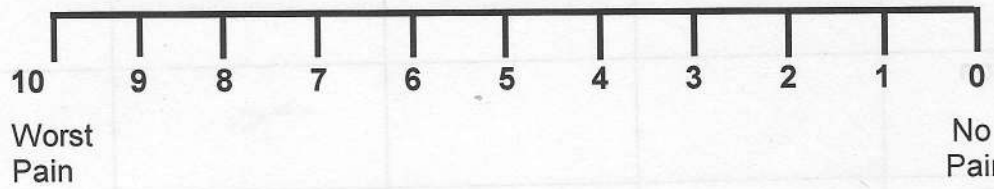
Signature of Candidate

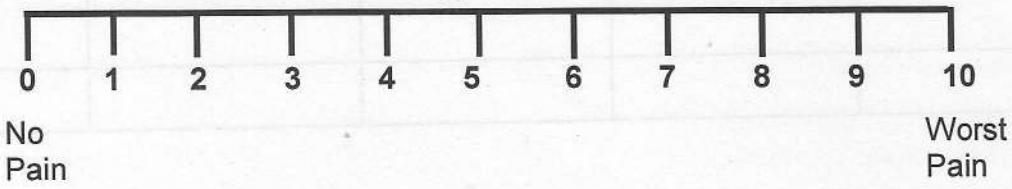
Signature of Supervisor

Modified observers assesment of alertness sedation scale – MOSS A

Score	Responsivness
6	Agitated
5	Responds readily to name spoken in normal tone
4	Lethargic response to name spoken in normal tone
3	Responds only after name is called loudly and/or repeatedly
2	Responds only after mild prodding or shaking
1	Does not respond to mild prodding or shaking
0	Does not respond to deep stimulus

NUMERICAL RATING SCALE (PAIN SCALE)





Signature of Candidate **Signature of Supervisor**

INFORMED PATIENT CONSENT

Date: _____

I.....D/o, W/o,

S/o..... .....am willing to participate in the study **"COMPARATIVE EVALUATION OF PHENIRAMINE VERSUS HYOSCINE FOR MANAGEMENT OF POST – OPERATIVE CATHETER RELATED BLADDER DISCOMFORT AFTER GENERAL ANAESTHESIA"** The procedure with its complications has been explained to me in local vernacular language. I have fully understood that no special tests and extra expenditure in any form, merely for the purpose of thesis is being carried out. I am free to opt out the study any time without assigning any reason.

....

Signature of the Witness Signature of the patient

Name:

Signature of Supervisor **Signature of Candidate**

मरीज अनुमति फार्म

तिथि _____

मैं _____ पत्नी/पुत्र/पुत्री _____ निवासी _____ इस शोधकार्य **"COMPARATIVE EVALUATION OF PHENIRAMINE VERSUS HYOSCINE FOR MANAGEMENT OF POST – OPERATIVE CATHETER RELATED BLADDER DISCOMFORT AFTER GENERAL ANAESTHESIA"** में भाग लेने के लिए सहमत हूँ। मैं इस शोधकार्य में भाग लेने के लिए अपनी स्वेच्छा से तैयार हूँ। मैं पुष्टि करता/करती हूँ की यह स्वीकृति देने के लिए मुझे कोई आर्थिक प्रलोभन नहीं दिया गया और न ही दबाव डाला गया है। मुझे इस शोधकार्य का उद्देश्य स्पष्ट कर दिया गया है और मुझे यह विश्वास है की यह विज्ञान और मानवता के लाभ के लिए है। मुझे इस शोधकार्य में होने वाले जोखिम के बारे में समझा दिया गया है और मेरी समझ में यह जोखिम बहुत मामुली है।

मैं इस शोधकार्य में भाग लेने के सम्बन्ध में किसी भी समय अपनी अस्वीकृति व्यक्त कर सकता/सकती हूँ और मेरे अस्वीकृति व्यक्त करने का मेरे इलाज पर कोई प्रभाव नहीं पड़ेगा।

_____ _____

गवाह के हस्ताक्षर रोगी के हस्ताक्षर/अंगूठे का निशान

नाम: नाम:

_____

अन्वेषक के हस्ताक्षर

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विद्यार्थी के हस्ताक्षर

ਮਰੀਜ਼ ਰਜ਼ਾਮੰਦੀ ਫਾਰਮ

ਮਿਤੀ_____

ਮੈ_____ਪਤਨੀ/ਪੁੱਤਰ/ਪੁੱਤਰੀ_____ਵਾਸੀ

_____

"COMPARATIVE EVALUATION OF PHENIRAMINE VERSUS HYOSCINE FOR MANAGEMENT OF POST – OPERATIVE CATHETER RELATED BLADDER DISCOMFORT AFTER GENERAL ANAESTHESIA" ਤੇ ਚਲ ਰਹੀ ਖੋਜ ਵਿਚ ਹਿੱਸਾ ਲੈਣ ਲਈ ਰਜ਼ਾਮੰਦ ਹਾਂ। ਇਸ ਖੋਜ ਕੰਮ ਵਿਚ ਹਿੱਸਾ ਲੈਣ ਲਈ ਮੈ ਆਪਣੀ ਮਰਜ਼ੀ ਨਾਲ ਤਿਆਰ ਹਾਂ। ਮੈ ਇਹ ਦਸਣਾ ਚਾਹੁੰਦਾ ਹਾਂ/ ਚਾਹੁੰਦੀ ਹਾਂ ਕੇ ਇਹ ਰਜ਼ਾਮੰਦੀ ਦੇਣ ਵਾਸਤੇ ਮੈਨੂ ਕਿਸੇ ਵੀ ਤਰਾਂ ਦਾ ਲੋਭ-ਲਾਲਚ ਨਹੀ ਦਿੱਤਾ ਗਿਆ ਅਤੇ ਨਾ ਹੀ ਕੋਈ ਦਬਾ ਪਾਇਆ ਗਿਆ ਹੈ। ਮੈਨੂ ਇਸ ਖੋਜ ਦਾ ਮਨੋਰਥ ਸਮਝਾ ਦਿੱਤਾ ਗਿਆ ਹੈ ਅਤੇ ਮੈਨੂ ਇਹ ਭਰੋਸਾ ਦਵਾਇਆ ਗਿਆ ਹੈ ਕੇ ਇਹ ਖੋਜ ਵਿਗਿਆਨ ਅਤੇ ਮਾਨਵਤਾ ਦੀ ਭਲਾਈ ਲਈ ਹੈ। ਮੈਨੂ ਇਸ ਖੋਜ ਵਿਚ ਹੋਣ ਵਾਲੇ ਖਤਰੇ ਬਾਰੇ ਸਮਝਾ ਦਿੱਤਾ ਗਿਆ ਹੈ ਅਤੇ ਮੈਨੂ ਇਹ ਯਕੀਨ ਹੈ ਕੇ ਇਹ ਖਤਰਾ ਬਹੁਤ ਮਾਮੂਲੀ ਹੈ। ਮੈਨੂ ਇਸ ਖੋਜ ਕੰਮ ਵਿਚ ਹਿੱਸਾ ਲੈਣ ਦਾ ਢੰਗ – ਤਰੀਕਾ ਸਮਝਾ ਦਿੱਤਾ ਗਿਆ ਹੈ।

ਮੈ ਇਸ ਖੋਜ ਕੰਮ ਵਿਚ ਹਿੱਸਾ ਲ਼ੈਣ ਬਾਰੇ ਆਪਣੀ ਰਜ਼ਾਮੰਦੀ ਕਿਸੇ ਵੀ ਸਮੇ ਵਾਪਸ ਲੈ ਸਕਦਾ ਹਾਂ/ ਸਕਦੀ ਹਾਂ ਅਤੇ ਮੇਰੀ ਰਜ਼ਾਮੰਦੀ ਵਾਪਸ ਲੈਣ ਦਾ ਮੇਰੇ ਇਲਾਜ ਤੇ ਕੋਈ ਅਸਰ ਨਹੀ ਹੋਵੇਗਾ।

_____ _____

ਗਵਾਹ ਦੇ ਹਸਤਾਖਰ ਮਰੀਜ਼ ਦੇ ਹਸਤਾਖਰ

ਮਿਤੀ_____ ਮਿਤੀ_____

ਪਤਾ _____ ਪਤਾ _____

_____

ਨਿਰੀਖਕ ਦੇ ਹਸਤਾਖਰ

_____

ਸਿਖਿਆਰਥੀ ਦੇ ਹਸਤਾਖਰ